

Denise M. Elser, M.D.

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KATHRYN E. CORBET and ERIC R. CORBET,) SUPERIOR COURT OF NEW JERSEY LAW DIVISION - BERGEN COUNTY DOCKET NO. BER-L-14589-14MCL
Plaintiffs,)
vs.) MASTER DOCKET NO. BER-L-11575-14
)
ETHICON, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, A Division of Ethicon, Inc., GYNECARE, JOHNSON & JOHNSON AND JOHN DOES 1-20,) CIVIL ACTION In Re Pelvic Mesh/Gynecare Litigation
Defendants.) Case No. 291 CT

The video-recorded deposition of DENISE M. ELSER, M.D., taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the Le Meridien Chicago - Oakbrook Center, Discovery Boardroom, 9th Floor, 2100 Spring Road, Oak Brook, Illinois, on November 5, 2015, at 9:14 a.m.

EXHIBIT C

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
Deps@golkow.com

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1	A P P E A R A N C E S	E X H I B I T S
2	PRESENT ON BEHALF OF THE PLAINTIFFS:	ELSER EXHIBIT MARKED FOR ID
3	SEEGER WEISS, LLP	Exhibit 1 Notice of Video Deposition of 7 Denise M. Elser, MD
4	77 Water Street	5 Pages
5	New York, New York 10005	Exhibit 2 12/9/14 Invoice to Burt Snell 13 from Denise M. Elser, MD
6	888.610.6574	1 Page
7	BY: JEFFREY S. GRAND, ESQ. jgrand@seegerweiss.com	Exhibit 3 Expert Report of 32 Denise M. Elser, MD
8	PRESENT ON BEHALF OF THE DEFENDANTS:	59 Pages
9	BUTLER SNOW, LLP	Exhibit 4 Supplemental TVT and Corbet Case 37 Expert Report of
10	500 Office Center Drive, Suite 400	Denise M. Elser, MD
11	Fort Washington, Pennsylvania 19034	Exhibit 5-A Disk, "Ethicon Gynecare Pelvic 54 Mesh Litigation, Additional
12	267.513.1885	Medical Records & Transcripts
13	BY: NILS B. (BURT) SNELL, ESQ.	Corbet 8/25/15"
14	burt.snell@butlersnow.com	Exhibit 5-B Disk, "Corbet Ethicon Gynecare 54 Pelvic Mesh Litigation"
15	VIDEOGRAPHER:	Exhibit 5-C Disk, "Ethicon Gynecare Pelvic 54 Mesh Litigation (Edwards) 6/2/15"
16	MILO SAVICH	Exhibit 5-D Disk, "Ethicon Gynecare Pelvic 54 Mesh Litigation TVT-O"
17	Golkow Technologies	Exhibit 5-E Disk, "New Prolift/POP Studies 54 7/31/15"
18	REPORTED BY:	Exhibit 5-F Disk, "Ethicon Gynecare Pelvic 54 Mesh Litigation 7/31/15"
19	PAULINE M. VARGO, RPR, CRR	Exhibit 5-G Disk, "Ethicon Gynecare Pelvic 54 Mesh Litigation (Edwards) 6/2/15"
20	Illinois CSR No. 84-1573.	
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11		Exhibit 13 Summary Report from Cochrane 110 Website, 5 Pages (Initially marked as Exhibit 10, re-marked as Exhibit 13 at Page 159.)
12	REQUESTS FOR PRODUCTION	Exhibit 14 AUA Guideline for the Surgical 157 Management of Female Stress
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<p style="text-align: right;">Page 6</p> <p>1 THE VIDEOGRAPHER: We are now on the 2 record. My name is Milo Savich, and I'm a 3 videographer for Golkow Technologies. Today's 4 date is November 5th, 2015, and the time on 5 record is 9:14 a.m.</p> <p>6 This video deposition is being held 7 in Oak Brook, Illinois, in the matter of 8 Kathryn E. Corbet, et al., versus Ethicon, 9 Inc., et al., for the Superior Court of New 10 Jersey, Law Division, Bergen County.</p> <p>11 The deponent is Dr. Denise M. Elser. 12 Will counsel please identify 13 themselves for the record.</p> <p>14 MR. GRAND: Jeff Grand from Seeger 15 Weiss for Kathryn Corbet.</p> <p>16 MR. SNELL: Burt Snell from Butler 17 Snow for Defendants Ethicon and Johnson & 18 Johnson.</p> <p>19 THE VIDEOGRAPHER: The court reporter 20 today is Pauline Vargo, who will now swear in 21 the witness and we may then proceed.</p> <p>22 THE REPORTER: Raise your right hand, 23 please. 24 (The witness was duly sworn.) 25</p>	<p style="text-align: right;">Page 8</p> <p>1 BY MR. GRAND: 2 Q. First off, I will mark as Exhibit 1 a 3 copy of the deposition notice for today. 4 Have you seen this before?</p> <p>5 A. I have. 6 Q. I would like to go to Exhibit A, which I 7 believe is the third page. I sort of want to run 8 through this and see what you may have brought with 9 you today or do not have. 10 With respect to number 1, documents 11 related to your fees, billing and time spent in 12 connection with your opinions in any pelvic mesh 13 litigation, have you brought that here today?</p> <p>14 A. I have brought a copy of an invoice 15 related to writing of the original report on this 16 case, so I would have that with me. 17 Q. Okay. Let's stop for a second, and have 18 you -- when was the last time you were deposed on 19 a -- for the TTVT product in a case relating -- 20 involving the TTVT product? 21 A. The last deposition -- 22 Q. Yes. 23 A. -- was the one we did. I don't remember 24 the date. 25 Q. You don't remember the date?</p>
<p style="text-align: right;">Page 7</p> <p>1 DENISE M. ELSE, M.D., 2 called as a witness herein, having been first duly 3 sworn, was examined and testified as follows: 4 EXAMINATION 5 BY MR. GRAND: 6 Q. Good morning, Dr. Elser. My name is 7 Jeffrey Grand. I'm here to ask you some questions 8 today on behalf of Plaintiffs Kathleen Corbet -- 9 Kathryn Corbet. Sorry. 10 I know you have been deposed before -- 11 A. Yes. 12 Q. -- so I'm not going to waste your time 13 going through all the rules again. Let me just say 14 if you feel like you need a break at any time, just 15 let me know. I will be happy to accommodate you. 16 I only ask that if we are in the middle of a 17 question and answer that we finish it before we 18 break. 19 If I ask something that doesn't make 20 sense to you or in a confusing way, which is highly 21 probable, I ask just let me know and I will try to 22 reframe my question. 23 A. Okay. 24 (Elser Exhibit 1 was marked for 25 identification as of 11/5/15.)</p>	<p style="text-align: right;">Page 9</p> <p>1 A. I don't. 2 Q. How many times have you been deposed? 3 How many times have you served as an expert for 4 TTVT? 5 A. For TTVT, twice before. 6 Q. Twice before. And have you served as an 7 expert since the time you were retained to serve as 8 a consultant in this case? 9 A. No. 10 Q. Have you served as an expert in mesh 11 litigation involving any other Ethicon mesh 12 products? 13 A. For a Prolift case. 14 Q. Prolift case. And which case was that? 15 A. I don't remember the patient's name. 16 Q. And did you sit for a deposition in that 17 case? 18 A. I don't think so. 19 Q. Have you served as an expert in cases 20 involving any other -- any of the other TTVT 21 products, such as TTVT Secur or the TTVT-O? 22 A. There was a TTVT-O case. 23 Q. TTVT-O case. And do you remember the 24 name of that case? 25 A. No.</p>

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<p>1 Q. Just correct me if I'm wrong. Did you 2 say that you have been an expert for two other TVT 3 cases?</p> <p>4 A. Correct. I was including the TVT-O in 5 that.</p> <p>6 Q. Okay. So --</p> <p>7 A. I took that -- sorry. I took your 8 question as TVT family.</p> <p>9 Q. I'm sorry if I wasn't clear. 10 For the purposes of today, it's actually 11 a good point, I'm going to refer to specific -- the 12 specific product. So, if I say TVT, I am not -- 13 unless I say otherwise, I'm not referring to the 14 TTV family of products. I would be referring to 15 the TVR retropubic.</p> <p>16 A. So, if you say "TVT," then you mean the 17 original TTV.</p> <p>18 Q. The retropubic.</p> <p>19 A. And if you say "Exact" you are going to 20 say Exact. Okay.</p> <p>21 Q. Okay. And Dr. Elser, when did -- when 22 were you first retained to be a TTV consultant, an 23 expert in any mesh litigation?</p> <p>24 A. I don't remember the date. A few years 25 ago.</p>	<p>1 devices to treat SUI or pelvic organ prolapse? 2 A. So, I'm sorry, can you -- am I working 3 on developing new products? No.</p> <p>4 Q. So, it would be fair to say that your 5 consultation today, as of this time, is limited to 6 litigation consulting for Ethicon and Johnson & 7 Johnson?</p> <p>8 A. Yes.</p> <p>9 Q. Are you currently a speaker for Johnson 10 & Johnson or Ethicon?</p> <p>11 A. No.</p> <p>12 Q. Do you do any trainings for Johnson & 13 Johnson or Ethicon?</p> <p>14 A. No.</p> <p>15 Q. And do you recall when you were first 16 retained to work on the Corbet case?</p> <p>17 A. I know I worked on the original report 18 in July. I don't remember if that was the first 19 time I started working on it, but that was when I 20 wrote the report.</p> <p>21 Q. Well, your first report was submitted in 22 July of 2014, correct?</p> <p>23 A. Correct.</p> <p>24 Q. Do you recall how long it took you to 25 prepare that report?</p>
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<p>1 Q. Can we narrow that down? Was it 2012? 2 A. That sounds right.</p> <p>3 MR. SNELL: Just note for the record 4 this was covered in the original deposition. 5 Just, I mean, I don't know if you read it, but 6 I think there is a date in that deposition 7 where she did.</p> <p>8 MR. GRAND: Yeah, I'm not doubting 9 that. I'm just trying to find out what she 10 has done since then.</p> <p>11 MR. SNELL: No, I don't care. I'm 12 just saying for the record reference, I mean, 13 there is a prior deposition where that date 14 may be available.</p> <p>15 BY MR. GRAND:</p> <p>16 Q. Have you served as an expert consultant 17 for any other mesh products besides Ethicon 18 products?</p> <p>19 A. No.</p> <p>20 Q. Do you currently serve as a consultant 21 to any other mesh manufacturer other than Johnson & 22 Johnson?</p> <p>23 A. No.</p> <p>24 Q. Are you currently involved in any -- in 25 the development of any Johnson & Johnson medical</p>	<p>1 A. I would look at my invoice to see 2 because I already wrote down my hours for that. 3 It's in the invoice.</p> <p>4 Q. Why don't we get that out if it will 5 refresh your recollection.</p> <p>6 A. Okay.</p> <p>7 MR. SNELL: Do you just want to tell 8 me where it is?</p> <p>9 THE WITNESS: It was on the top of 10 that box, just free-floating paper. (Document tendered to the witness.)</p> <p>12 BY THE WITNESS:</p> <p>13 A. So, I worked a total on this, including 14 record review, literature search and writing the 15 report, phone consultations was 40 -- 62 hours.</p> <p>16 THE REPORTER: 40?</p> <p>17 THE WITNESS: 62.</p> <p>18 MR. GRAND: And that's -- is that a 19 copy of that for me?</p> <p>20 MR. SNELL: You can mark it.</p> <p>21 MR. GRAND: Why don't we just mark 22 this as Exhibit 2, and for the record, I'm 23 marking an invoice to Burt Snell of Butler 24 Snow from Dr. Elser dated December 9th, 2014. (Elser Exhibit 2 was marked for</p>

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<p>1 identification as of 11/5/15.)</p> <p>2 BY MR. GRAND:</p> <p>3 Q. And have you prepared an invoice for the</p> <p>4 preparation of your supplemental report?</p> <p>5 A. I have not.</p> <p>6 Q. Can you tell me how many hours you spent</p> <p>7 preparing your supplemental report?</p> <p>8 A. I'm estimating 25 to 30.</p> <p>9 Q. Well, your initial report -- your</p> <p>10 initial report took -- never mind. Strike that.</p> <p>11 Then when did you begin work on the</p> <p>12 supplemental report?</p> <p>13 A. Last week on Monday.</p> <p>14 Q. So you did not begin any work on the</p> <p>15 supplemental report until Monday of last week?</p> <p>16 A. Well, I'm always reading the literature,</p> <p>17 always having articles that I may want to pull into</p> <p>18 reports, but as I looked at the renewed records</p> <p>19 that came in on this case, that's when I started</p> <p>20 specifically working on writing the report.</p> <p>21 Q. And were you asked -- were you asked by</p> <p>22 counsel to submit a supplemental report?</p> <p>23 A. I believe so.</p> <p>24 Q. And was that on or about Monday of last</p> <p>25 week?</p>	<p>1 I'm just asking.</p> <p>2 MR. SNELL: But she did produce -- in</p> <p>3 the prior deposition she produced invoices.</p> <p>4 Didn't you?</p> <p>5 THE WITNESS: I don't remember.</p> <p>6 MR. SNELL: It's my recollection that</p> <p>7 she did.</p> <p>8 BY MR. GRAND:</p> <p>9 Q. Do you know how many hours this year</p> <p>10 apart from your work on the Corbet case you have</p> <p>11 spent on mesh litigation?</p> <p>12 A. No.</p> <p>13 Q. It would be less than 50?</p> <p>14 A. Less than 50 hours total? No. I think</p> <p>15 it's more than 50.</p> <p>16 Q. Well, you estimated probably about 30</p> <p>17 for your supplemental report?</p> <p>18 A. Correct.</p> <p>19 Q. You aren't working on the Corbet</p> <p>20 supplemental report at any point this year prior to</p> <p>21 last week, were you?</p> <p>22 A. No.</p> <p>23 Q. So, prior to last week, any hours you've</p> <p>24 spent as a mesh consultant has been for another</p> <p>25 case?</p>
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<p>1 A. Yes.</p> <p>2 Q. So after this deposition was noticed,</p> <p>3 you were asked to supplement your report?</p> <p>4 A. Yes.</p> <p>5 Q. Presently my understanding is you have a</p> <p>6 busy practice, correct?</p> <p>7 A. Yes.</p> <p>8 Q. About how many hours a week do you</p> <p>9 devote to your practice?</p> <p>10 A. About 60.</p> <p>11 Q. And about how many hours a week do you</p> <p>12 typically devote to consulting work of any kind?</p> <p>13 A. Some weeks none, some weeks 30.</p> <p>14 Q. Have you prepared any estimates -- do</p> <p>15 you have invoices for any other cases you are</p> <p>16 working on as a mesh consultant?</p> <p>17 A. No, not with me.</p> <p>18 MR. GRAND: Are you guys objecting to</p> <p>19 producing that, Burt?</p> <p>20 MR. SNELL: Yeah. Your experts never</p> <p>21 produced all their invoices. I know, for</p> <p>22 example, Dr. Elliot has been paid probably</p> <p>23 over \$800,000 and I haven't received all his</p> <p>24 invoices.</p> <p>25 MR. GRAND: No need to make speeches.</p>	<p>1 A. Correct.</p> <p>2 MR. SNELL: Hold on. I'm going to put</p> <p>3 an objection on the record. She is a general</p> <p>4 expert and has issued general updated expert</p> <p>5 reports in other cases.</p> <p>6 MR. GRAND: Okay. Then let's break it</p> <p>7 out that way.</p> <p>8 BY MR. GRAND:</p> <p>9 Q. For your general report on the TVT, how</p> <p>10 many hours have you spent this year on that?</p> <p>11 A. I couldn't answer that right now. I</p> <p>12 would sit down and look at my records.</p> <p>13 Q. Have you issued a general -- a general</p> <p>14 report for any other Ethicon mesh products, such as</p> <p>15 the Prolift?</p> <p>16 A. No.</p> <p>17 Q. So, other than the TVT-O you have not</p> <p>18 written any other general reports?</p> <p>19 A. Correct.</p> <p>20 Q. And the general report that's been</p> <p>21 submitted in this case, the Corbet case, only</p> <p>22 applies to the TVT retropubic, correct?</p> <p>23 A. Yes.</p> <p>24 Q. If you look back at Exhibit A, which you</p> <p>25 still have in front of you, a copy of your</p>

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<p style="text-align: center;">Page 18</p> <p>1 up-to-date CV, is your -- have there been any 2 changes to your CV since, I guess, last week? 3 A. No. 4 Q. And the one that was attached to your 5 supplemental report was up to date? 6 A. Yes. 7 Q. Did you update that yourself? 8 A. Yes. 9 Q. In your own practice, I believe you 10 testified that you -- how many SUI procedures 11 involving mesh do you perform a year, would you 12 estimate? 13 A. In past years, it has been about 150. 14 This last year it was about 90. 15 Q. And what -- what different mesh products 16 do you recommend for your clients with SUI if you 17 are recommending a mesh sling? 18 MR. SNELL: Form, clients. 19 MR. GRAND: Sorry. Patients. 20 BY THE WITNESS: 21 A. Thank you. The slings that I use 22 currently are the TVT Exact, the Abbrevio, and I 23 also use MiniArc. 24 BY MR. GRAND: 25 Q. You do not currently use the TVT-R or</p>	<p style="text-align: center;">Page 20</p> <p>1 Q. I know. I'm just trying to... 2 And none of those hospitals currently 3 carry the TVT retropubic or the TVT-O? 4 A. I have not seen the product there in a 5 while. 6 Q. Have you ever discussed with anyone at 7 the hospital why they don't carry those products 8 any more? 9 A. No. 10 Q. Have you ever requested that they carry 11 those products? 12 A. No. I was happy with the transition to 13 the Exact and the Abbrevio. 14 Q. Now, you said with the exception of last 15 year, which I believe you said you have done about 16 90 procedures so far, you said on average you did 17 about 150 per year? 18 A. Correct. 19 Q. Do you use any mesh products other than 20 Ethicon products? 21 A. Are you saying for stress incontinence 22 or other indications? 23 Q. Yes, for stress incontinence. 24 A. So, the MiniArc is a AMS product. 25 Q. All right. Anything else?</p>
<p style="text-align: center;">Page 19</p> <p>1 the TVT-O? 2 A. Correct. 3 Q. And when did you stop using those 4 products? Strike that. 5 Did you ever use those products? 6 A. Yes, I did. 7 Q. Okay. When did you stop using those 8 products? 9 A. I don't know the date. It has been at 10 least two years. 11 Q. And why did you stop using those 12 products? 13 A. Mostly availability. 14 Q. And when you say availability, you mean 15 the products weren't available at the hospital in 16 which you worked? 17 A. Correct. 18 Q. And I'm sure I have it in your CV, but 19 what hospital do you work out of? 20 A. I operate out of four hospitals. 21 Q. Okay. 22 A. Christ Hospital is Oak Lawn, Good 23 Samaritan Hospital in Downers Grove, Edward 24 Hospital in Naperville and Elmhurst Hospital in 25 Elmhurst. That's all on my CV.</p>	<p style="text-align: center;">Page 21</p> <p>1 A. Occasionally a Boston Scientific sling, 2 the Advantage. 3 Q. And are there certain -- what drives 4 your decision to use one product as opposed to 5 another in a given patient? 6 A. Can you be more specific? Are you 7 talking about whether I would use the Advantage or 8 the Exact -- 9 Q. Yes. 10 A. -- or whether I would use the Exact 11 versus an obturator? 12 Q. I believe you said you don't use the 13 TVT-O any more, correct? 14 A. Well, Abbrevio is an obturator sling, so 15 I don't -- I don't understand what you are trying 16 to ask me. 17 Q. I'm not trying to focus in on the 18 approach necessarily. I'm just asking, is there -- 19 is there a particular reason why you might use one 20 product versus another with a patient that you were 21 recommending a sling for? 22 A. So, again, I'm finding that a little 23 vague. Do you want to know why I would use the 24 Advantage versus the Exact? 25 Q. Sure. Let's start there.</p>

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<p>1 A. Okay. It could be that there was one 2 Exact on the shelf and somebody dropped it when 3 they opened it and others, an Advantage is on the 4 shelf and I would use that, but it's not my 5 preferred.</p> <p>6 Q. Okay. So, is there -- do you view these 7 as being relatively comparable?</p> <p>8 A. Relatively, but different.</p> <p>9 Q. Have your billing rates changed? And 10 for litigation consulting, have your billing rates 11 changed since the last time you were deposed?</p> <p>12 A. I don't think so.</p> <p>13 Q. And I believe you said you have yet to 14 issue an invoice for the supplemental report, 15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. Now, with respect to your own, the mesh 18 procedures you perform, do you keep any internal 19 databases that track those clients? I mean, track 20 those patients.</p> <p>21 A. We have a EMR that has a lot of data in 22 it, so from time to time I will evaluate our 23 followup, how many cases we have done, which 24 product.</p> <p>25 Q. I guess let me just try to approach more</p>	<p>1 A. Over a year. 2 Q. I just want to be clear. Did you look 3 at a year-long period or did you look beyond a 4 year-long period?</p> <p>5 A. So, I don't remember what the time 6 period was. I know that my intention was to look 7 at a year after their incident, case.</p> <p>8 Q. Okay. So, just to be clear, I want to 9 make sure I understand what you are saying in your 10 report and here today. If, for example, last year 11 you did a hundred mesh procedures, a hundred mesh 12 procedures, you would have looked at a hundred 13 patients; you didn't go back beyond that --</p> <p>14 MR. SNELL: Form.</p> <p>15 Q. -- into prior years?</p> <p>16 MR. SNELL: Form objection. Go ahead.</p> <p>17 A. I would have looked at, say, the 18 patients that had surgery two years ago, over, 19 like, say 2013, so that even the ones at the end of 20 the year would have had a year followup. Does that 21 make sense?</p> <p>22 Q. Okay. So, are you saying that you -- 23 your 4.5 percent is over a two-year period from 24 implant?</p> <p>25 A. I wanted to make sure that the least</p>
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<p>1 directly what I'm trying to get at. I believe in 2 your report you said that you had a revision rate, 3 an erosion rate of about 4.5 percent --</p> <p>4 A. Yes.</p> <p>5 MR. SNELL: Objection.</p> <p>6 Q. -- for your clients -- for your 7 patients?</p> <p>8 MR. SNELL: Objection, compound, 9 misstates.</p> <p>10 A. I said a reoperation rate of 4-1/2 11 percent.</p> <p>12 Q. Okay. So a reoperation rate of any -- 13 for any reason?</p> <p>14 A. Correct.</p> <p>15 Q. How did you arrive at that 4.5 percent?</p> <p>16 A. I don't remember which dates I looked 17 at, but I pulled the data on a substantial number 18 of slings in our practice and then tracked how many 19 of those over a certain period of time went back 20 for reoperation.</p> <p>21 Q. Okay. What period of time did that 22 cover?</p> <p>23 A. I don't remember. I believe it was at 24 least a year.</p> <p>25 Q. Over a year? Just a year?</p>	<p>1 followup was a year.</p> <p>2 Q. Okay. But it could have been longer, 3 you are saying?</p> <p>4 A. Correct.</p> <p>5 Q. But you can't tell me that today. I 6 mean, how many patients did you look at in total?</p> <p>7 A. I don't remember.</p> <p>8 Q. Would you have any dates? Would you 9 have any notes or calculations in your office?</p> <p>10 A. Yes.</p> <p>11 MR. GRAND: We are going to request 12 production of those.</p> <p>13 THE WITNESS: Can I ask you a favor? 14 Because you say -- you are saying "mesh" 15 frequently and that makes me think of prolapse 16 surgery. So, if you mean sling, could you say 17 sling? Would that be okay?</p> <p>18 MR. GRAND: Sure. Believe me, I'm not 19 trying to intentionally be confusing, by any 20 means.</p> <p>21 THE WITNESS: You are probably used to 22 saying it that way, but it really throws me 23 off.</p> <p>24 MR. GRAND: I will do my best.</p> <p>25 MR. SNELL: And I will listen and</p>

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<p>1 object from now on when he is overbroad. I'm 2 sorry. I should have caught that.</p> <p>3 BY MR. GRAND:</p> <p>4 Q. All right. Just to be clear, so the 4.5 5 percent reoperation rate that you referred to in 6 your report, that refers to sling products or does 7 that also include other mesh products?</p> <p>8 A. That was slings.</p> <p>9 Q. That would be slings only.</p> <p>10 And your analysis included patients -- I 11 mean, generally you wanted to make sure you had a 12 year-long followup period?</p> <p>13 A. Correct.</p> <p>14 Q. But your analysis did not go back three 15 years or five years, did it?</p> <p>16 A. I will answer that when I look at the 17 report. I don't remember how far it went back.</p> <p>18 MR. SNELL: You can look at the report 19 too any time. I mean, you can always look at 20 your materials. You brought all them here to.</p> <p>21 BY MR. GRAND:</p> <p>22 Q. Did you bring those materials that 23 includes that calculation with you?</p> <p>24 A. No.</p> <p>25 MR. SNELL: I thought you said report.</p>	<p>1 patient previously and they are seeing somebody 2 else, you would have no way of knowing whether they 3 have had any subsequent complications?</p> <p>4 MR. SNELL: Form.</p> <p>5 A. Correct. There is some patients I won't 6 know what happened.</p> <p>7 Q. And did your analysis address anything 8 other than reoperations?</p> <p>9 A. No.</p> <p>10 Q. And if you were called to trial, do you 11 intend to testify about your 4.5 reoperation rate 12 in your practice?</p> <p>13 A. If you or Burt ask me.</p> <p>14 MR. GRAND: We are going to request 15 production of backup, whatever supports that.</p> <p>16 MR. SNELL: We will take it under 17 advisement. I will note for the record some 18 of your experts have made similar statements 19 yet have not produced the backup data.</p> <p>20 MR. GRAND: I don't know if you have 21 asked for them or not. I'm asking for it.</p> <p>22 MR. SNELL: I know. I'm just putting 23 my point on the record.</p> <p>24 BY MR. GRAND:</p> <p>25 Q. Other than what is in your CV, have you</p>
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<p>1 I'm sorry.</p> <p>2 THE WITNESS: I said the 4.5 percent 3 in the report, but I don't know that I 4 included all the details of what I looked at.</p> <p>5 MR. SNELL: My point is, you can look 6 at your -- he doesn't care if you -- I'm sure 7 you don't mind if she looks at her report.</p> <p>8 MR. GRAND: No.</p> <p>9 BY MR. GRAND:</p> <p>10 Q. In fact, I would rather you not guess, 11 and if you need to look at your report, you can. I 12 don't believe your report has any specifics other 13 than the 4.5 percent reoperation rate. That's why 14 I'm actually asking you these questions, because 15 I'm trying to determine how you arrived at that 4.5 16 percent number and what number of patients are 17 included in that.</p> <p>18 A. Understood. I don't think I put the 19 details in the report either.</p> <p>20 Q. Do you have any -- do you track data in 21 your office to determine how many of -- how many 22 patients in which you've implanted a mesh sling you 23 still currently treat?</p> <p>24 A. No.</p> <p>25 Q. So, if you implanted a mesh sling in a</p>	<p>1 done any -- have you published any articles 2 relating to mesh, mesh slings?</p> <p>3 A. Any -- any articles are in the CV.</p> <p>4 Q. Okay. There has been nothing since that 5 time?</p> <p>6 A. No.</p> <p>7 Q. And you don't currently -- are you 8 currently teaching any classes?</p> <p>9 A. Classes?</p> <p>10 Q. Yes.</p> <p>11 A. No.</p> <p>12 Q. Are you currently doing any research 13 relating for stress urinary incontinence?</p> <p>14 A. Yes.</p> <p>15 Q. What would that research be?</p> <p>16 A. We are studying a product called Vesair, 17 V-e-s-a-i-r.</p> <p>18 MR. SNELL: Before you go any further, 19 let me just caution you. If you are under any 20 confidentiality agreements, and I don't know 21 if you are or not, for other manufacturers, 22 you need to take that into account before you 23 give Mr. Grand an answer.</p> <p>24 THE WITNESS: Absolutely. I will not 25 disclose anything I'm not supposed to.</p>

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<p style="text-align: right;">Page 30</p> <p>1 BY THE WITNESS:</p> <p>2 A. So, I can't tell you any results of the 3 study, any data, but it is an intravesical balloon 4 that's put in in the office.</p> <p>5 BY MR. GRAND:</p> <p>6 Q. And that's not an Ethicon product, is 7 it?</p> <p>8 A. No.</p> <p>9 Q. Did you design the study?</p> <p>10 A. No.</p> <p>11 Q. And for how long have you been 12 conducting the study?</p> <p>13 A. Roughly a year.</p> <p>14 Q. Are you involved in any other research 15 relating to SUI or pelvic organ prolapse?</p> <p>16 A. The other study is a postmarketing study 17 for the Impressa.</p> <p>18 Q. How do you spell "Impressa"?</p> <p>19 MR. SNELL: Yeah, what is it?</p> <p>20 BY MR. GRAND:</p> <p>21 Q. That's not an Ethicon product, is it?</p> <p>22 A. No.</p>	<p style="text-align: right;">Page 32</p> <p>1 don't know which pile it's in.</p> <p>2 BY MR. GRAND:</p> <p>3 Q. So we are looking at the same thing, is 4 this your first report or the supplemental report?</p> <p>5 A. This is the first report, but I don't 6 see the CV in here, so I --</p> <p>7 Q. You can be -- you can -- well, I have 8 the copy that was in my report. I can give that to 9 you.</p> <p>10 A. That would be great.</p> <p>11 MR. GRAND: We will mark your July 12 2014 report as Elser 3. (Elser Exhibit 3 was marked for identification as of 11/5/15.)</p> <p>13 MR. GRAND: Did you want this?</p> <p>14 MR. SNELL: I will take it. I don't think I have her CV. If I did, it's somewhere in all of this stuff.</p> <p>15 MR. GRAND: So, I've got it. It's Attachment A.</p> <p>16 THE WITNESS: A lot of trees in this room.</p> <p>17 MR. GRAND: Yes.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Okay. Now I forgot what you asked. You</p>
<p style="text-align: right;">Page 31</p> <p>1 Q. No. And is that I-m-p-r-e-s-s-a?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Okay. You never know with these pharma 4 products.</p> <p>5 A. It's a Kimberly Clark product.</p> <p>6 Q. And is that -- is that a device or a 7 pharmaceutical product?</p> <p>8 A. Well, it's an over-the-counter device, 9 so it's basically an intravaginal tampon 10 specifically designed to put pressure on the 11 urethra so when women wear it they can exercise and 12 not leak.</p> <p>13 Q. And you are an investigator in that 14 study?</p> <p>15 A. Yes.</p> <p>16 Q. Did you design that study?</p> <p>17 A. No.</p> <p>18 Q. In general do you have -- do you have 19 any experience designing clinical trials?</p> <p>20 A. Yes.</p> <p>21 Q. What clinical trials have you designed?</p> <p>22 A. We can look at my CV.</p> <p>23 Q. If you want to, look at your CV.</p> <p>24 A. Sure. Hold on.</p> <p>25 THE WITNESS: Thank you, Burt. I</p>	<p style="text-align: right;">Page 33</p> <p>1 want to know what studies I had designed. Was that 2 specifically with regard to stress incontinence?</p> <p>3 BY MR. GRAND:</p> <p>4 Q. Well, actually, I would like to know if 5 you -- if you have ever designed a clinical study 6 as opposed to being an investigator for a clinical 7 study.</p> <p>8 MR. SNELL: Form. Go ahead.</p> <p>9 A. So, I'm on Page 4.</p> <p>10 Q. Okay.</p> <p>11 A. The last one on that page, abdominal 12 sacrocolpopexy and urinary incontinence, was my 13 design.</p> <p>14 Q. Was that a randomized control trial?</p> <p>15 A. No. That was a retrospective K series.</p> <p>16 Q. That was a retrospective K series?</p> <p>17 A. Yes. On the next page, Page 5, the last 18 two.</p> <p>19 Q. And what types of studies were those?</p> <p>20 A. The comparison of the different 21 catheters was a randomized controlled trial. 22 And the last study was also an RCT, 23 which I helped design as part of the continence 24 program for women, and that's it on this page. The 25 others were not published.</p>

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<p>Page 34</p> <p>1 Q. Do you currently sit as a reviewer for 2 any medical journals? 3 A. Yes. 4 Q. Which ones? 5 A. The International Urogynecologic 6 Journal, The Obstetrics and Gynecology Journal, The 7 American Journal of Obstetrics and Gynecology and 8 Female Pelvic Medicine Reconstructive Surgery. 9 Q. And actually, while you have your resume 10 open, if you look at -- sorry -- Page 4. I just 11 wanted to clarify. The consultation for the Food 12 and Drug Administration panel -- 13 A. Yes. 14 Q. -- did that begin in 2013 or was it 15 2014? 16 A. They do background checks, so they first 17 asked me to be part of it in 2013. 18 Q. Okay. So but the first time you sat on 19 a panel was 2014, correct? 20 A. Yes -- no. Sorry. The first time I sat 21 on it was 2015. 22 Q. 2015, okay. And you are a nonvoting 23 member, correct? 24 A. Correct. 25 Q. Would you hold yourself out as an expert</p>	<p>1 clinical trial design. 2 A. I have had statistic courses, and then 3 throughout our training and working career we have 4 journal club where we talk about how to analyze 5 articles. 6 Q. When was the last time you had a 7 statistics course? 8 A. Oh. 15 years ago. 9 Q. And can you tell me a little bit more 10 about this journal club you just referenced. 11 A. In our practice we will have meetings 12 where we pull articles to read and discuss them 13 with other physicians and have someone analyze the 14 article. 15 Q. And what's the name of that journal 16 club? 17 A. It doesn't have a name. It's just our 18 practice and we have -- 19 Q. So you do that within your private 20 practice? 21 A. Yes. 22 Q. Okay. So, you get together with the 23 physicians in your practice and you discuss 24 articles? 25 A. Correct.</p>
<p>Page 35</p> <p>1 in clinical trial design? Do you consider yourself 2 an expert in clinical trial design? 3 A. I'm very familiar with clinical trial 4 design, but it's not what I do on a regular basis. 5 Q. So is that a no? 6 MR. SNELL: I object to the form, 7 asked and answered. 8 Q. Do you hold yourself out as an expert in 9 clinical trial design? 10 A. I understand clinical trial design. I'm 11 not an expert in it. 12 Q. What about material science? Do you 13 consider yourself an expert in material science? 14 A. No. 15 Q. Do you consider yourself an expert in 16 the design of medical devices? 17 A. No. 18 Q. Do you consider yourself an expert in 19 epidemiology? 20 A. No. 21 Q. Have you received special training with 22 respect to analyzing clinical -- analyzing and 23 evaluating clinical studies? 24 A. What do you mean by "special training"? 25 Q. Courses in epidemiology or statistics or</p>	<p>Page 37</p> <p>1 Q. How often does that happen? 2 A. Every few months. 3 Q. Every few months. I would like to mark 4 as -- 5 A. Does that mean I can close this one now, 6 that page? 7 Q. Yes. 8 A. That page? Okay. 9 Q. Yeah. If it is easier for you to refer 10 to your report moving forward, please feel free to 11 do so. I just want to have a copy of your report 12 in the record. 13 MR. GRAND: I'm going to mark as 14 Elser 4 your supplemental report. 15 (Elser Exhibit 4 was marked for 16 identification as of 11/5/15.) 17 BY MR. GRAND: 18 Q. Do you need a copy of that? 19 A. I have a copy here. 20 Q. Now, in your first report from July of 21 2014 you had reserved the right to supplement your 22 report based on new information -- 23 A. Yes. 24 Q. -- in response to Plaintiffs' experts, 25 as I recall. Is that correct?</p>

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<p>1 A. Correct.</p> <p>2 Q. And one of the things that was revised 3 in your supplemental report was the list of 4 materials you relied on, correct?</p> <p>5 A. Correct.</p> <p>6 Q. Okay. Did you prepare that reliance 7 list?</p> <p>8 A. It was a combination.</p> <p>9 Q. A combination of what?</p> <p>10 A. Of some were provided to me by the 11 attorneys and there were many articles that I 12 pulled and provided to them.</p> <p>13 Q. Okay. Just to be clear, I'm actually -- 14 I will ask about that. I'm going to ask 15 specifically about the preparation of the list 16 itself. Did you prepare the reliance list, or was 17 that prepared by attorneys?</p> <p>18 MR. SNELL: You mean the paper?</p> <p>19 MR. GRAND: Yeah, the actual list that 20 was submitted.</p> <p>21 MR. SNELL: We prepared that. I will 22 put that on the record.</p> <p>23 BY MR. GRAND:</p> <p>24 Q. Okay. Were you aware that there were 25 approximately 575 new medical articles added to</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. So, if you look about the fifth 3 from the bottom on your revised list, which is the 4 one on your left, you see that "Abdel-Fattah, 5 Transobturator tension-free vaginal tapes: Are 6 they the way forward"? Do you see that article?</p> <p>7 A. Yes.</p> <p>8 Q. Dated 2007?</p> <p>9 A. Yes.</p> <p>10 Q. Do you see that article in your original 11 reliance list?</p> <p>12 A. No, I don't see that one.</p> <p>13 Q. That was an article that was certainly 14 available at the time that you wrote your original 15 report, correct?</p> <p>16 A. Yes. It had already been printed, but 17 sometimes when you do a literature search not 18 everything may show up. You may find new articles 19 even if they were printed previously.</p> <p>20 Q. Would it surprise you if the majority -- 21 that the majority of the ones you added were 22 available many, many years before you wrote your 23 report?</p> <p>24 A. I don't know. I have not analyzed that 25 yet.</p>
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<p>1 that list?</p> <p>2 MR. SNELL: I'm going to object it 3 lacks foundation.</p> <p>4 Q. All right. We will go through them one 5 by one. I want you to put both your reports beside 6 you there so that you can compare the reliance list 7 in the original report to the one in your 8 supplemental report.</p> <p>9 A. Okay. I start -- this doesn't look like 10 the page that you have.</p> <p>11 Q. No. I'm looking at the second report, 12 the supplemental report.</p> <p>13 A. Okay. I'm with you.</p> <p>14 Q. So, before we actually look at those, 15 when you were preparing your report, did you -- 16 when you first drafted this report for the Corbet 17 case, the original report, how did you seek to 18 identify articles that would be relevant to your 19 opinions?</p> <p>20 A. Some I knew existed from prior reading, 21 so I pulled and printed them to have available. 22 Some I did literature search to look for articles I 23 thought would be relevant, and some were provided 24 to me.</p> <p>25 Q. Some were provided to you by attorneys?</p>	<p>1 Q. Do you have a copy of this article in 2 your file? You brought your file here today.</p> <p>3 A. I don't know if that one is in it or 4 not.</p> <p>5 Q. Are all the articles you relied on in 6 your file?</p> <p>7 A. Not everything from this reliance list 8 is in my file, but there are many articles in the 9 file.</p> <p>10 Q. If you didn't rely on it, why would it 11 be in your file?</p> <p>12 A. Some of these are here because they were 13 provided and some were ones that I've read in the 14 past. I may not specifically have cited it in the 15 report.</p> <p>16 Q. So there may be articles in your 17 reliance list that have nothing to do with your 18 opinions?</p> <p>19 MR. SNELL: Form.</p> <p>20 A. There could be.</p> <p>21 Q. Did you review this list before it 22 was -- the revised list before it was submitted?</p> <p>23 A. I looked at it.</p> <p>24 Q. You know there are a number of articles 25 relating to the Prolift product in there?</p>

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<p>1 A. Yes.</p> <p>2 Q. Is that relative to your opinions in</p> <p>3 this case?</p> <p>4 A. Not in this case.</p> <p>5 Q. Then why did you have it in your report?</p> <p>6 MR. SNELL: I told you, we prepared</p> <p>7 that.</p> <p>8 MR. GRAND: Okay. Well, it's her</p> <p>9 report, though. Either she knows or she</p> <p>10 doesn't know.</p> <p>11 MR. SNELL: That's fine.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No. This list was prepared, was printed</p> <p>14 by the attorneys' office. I did not -- some</p> <p>15 articles were added.</p> <p>16 BY MR. GRAND:</p> <p>17 Q. So, is it fair to say this really isn't</p> <p>18 a reliance list for your report?</p> <p>19 A. Are you saying this is not the list</p> <p>20 specific to my report?</p> <p>21 Q. Yes.</p> <p>22 A. Some of the articles are not specific to</p> <p>23 this report.</p> <p>24 Q. So, this list actually just is all the</p> <p>25 articles you may have reviewed or had sent to you</p>	<p>1 MR. SNELL: She told you to pull that</p> <p>2 stuff is --</p> <p>3 MR. GRAND: She has to go through it.</p> <p>4 MR. SNELL: Well, we will try to go</p> <p>5 through it then at a break or at lunch. How</p> <p>6 about that?</p> <p>7 MR. GRAND: Okay.</p> <p>8 MR. SNELL: She has already said the</p> <p>9 Prolift stuff isn't -- isn't going to be</p> <p>10 discussed or pertinent.</p> <p>11 BY MR. GRAND:</p> <p>12 Q. Have you read all the articles that are</p> <p>13 on this list?</p> <p>14 A. Not every article.</p> <p>15 Q. What?</p> <p>16 A. Not every article.</p> <p>17 Q. If you go several pages in, beyond the</p> <p>18 medical articles, do you see there is a list of</p> <p>19 documents?</p> <p>20 MR. SNELL: What page are you -- which</p> <p>21 one are you referring to?</p> <p>22 MR. GRAND: It's not numbered.</p> <p>23 MR. SNELL: The one that's -- are you</p> <p>24 talking about production materials or other</p> <p>25 material? I mean, they are labeled at the</p>
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<p>1 by attorneys?</p> <p>2 A. Correct.</p> <p>3 Q. So if I wanted to know which articles in</p> <p>4 here you viewed as new information or material that</p> <p>5 you've reviewed in response to the Plaintiffs'</p> <p>6 expert reports, how would I be able to identify</p> <p>7 that?</p> <p>8 A. Well, I would be happy to mark up a copy</p> <p>9 for you and get it to you.</p> <p>10 Q. Okay. I am going to request that, and</p> <p>11 I'm not trying to be difficult. I'm trying to</p> <p>12 understand what you will be talking about when you</p> <p>13 come to trial as opposed to what is completely</p> <p>14 irrelevant to your report.</p> <p>15 A. Okay.</p> <p>16 Q. I'm expecting you can. I don't want to</p> <p>17 spend the day going through this list one by one.</p> <p>18 A. Are you sure?</p> <p>19 MR. SNELL: Well, we can do that. She</p> <p>20 is here to help you or to do whatever you</p> <p>21 want, and you have her report where she cites</p> <p>22 to articles and discusses them. So, you know,</p> <p>23 if you want to ask her, ask her.</p> <p>24 MR. GRAND: She just told me she</p> <p>25 doesn't know.</p>	<p>1 top.</p> <p>2 MR. GRAND: Yes, it would be</p> <p>3 production materials.</p> <p>4 BY MR. GRAND:</p> <p>5 Q. Do you see it? Are you there?</p> <p>6 A. Starts with letter to the FDA -- from</p> <p>7 the FDA?</p> <p>8 Q. Yes. That would be the first item on</p> <p>9 that list. Have you reviewed all the materials on</p> <p>10 this list?</p> <p>11 A. No. I have reviewed several but not</p> <p>12 every one.</p> <p>13 Q. Is it fair to say if you didn't review</p> <p>14 it, you certainly didn't rely on it, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And then after that is a list of medical</p> <p>17 records and as well as other types of materials and</p> <p>18 the expert reports. Do you see that?</p> <p>19 A. Not yet.</p> <p>20 Q. If you keep going, I think it is</p> <p>21 probably the next page.</p> <p>22 A. Yeah, I think I'm getting there, yeah.</p> <p>23 Okay.</p> <p>24 Q. Now, is this -- is this an update to the</p> <p>25 list of medical records you reviewed, or are these</p>

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<p>1 new records you reviewed since the last report?</p> <p>2 A. No. Some of these I would have reviewed</p> <p>3 for the original report.</p> <p>4 Q. Okay. And have you seen or reviewed the</p> <p>5 IME report that was done by Dr. Fleischmann?</p> <p>6 A. No.</p> <p>7 Q. Would that be relevant to your opinions?</p> <p>8 A. I would be interested in her findings.</p> <p>9 Q. Well, she conducted --</p> <p>10 A. My opinions are based on the exams to</p> <p>11 date and medical records provided to me.</p> <p>12 Q. Okay. Were you aware that last month</p> <p>13 Dr. Fleischmann conducted a medical examination of</p> <p>14 Kathryn Corbet?</p> <p>15 A. I only just heard about it.</p> <p>16 Q. Okay. When did you hear about it?</p> <p>17 A. This morning.</p> <p>18 Q. Okay. Did you request a copy of the</p> <p>19 examination?</p> <p>20 A. No, not yet.</p> <p>21 Q. It would certainly be relevant to your</p> <p>22 opinion, correct?</p> <p>23 A. It might be.</p> <p>24 Q. Well, for instance, if she were</p> <p>25 suffering -- if she had complaint of dyspareunia,</p>	<p>1 little long.</p> <p>2 MR. GRAND: I'm not trying to hold you</p> <p>3 to doing that in ten minutes.</p> <p>4 THE WITNESS: We want to do it</p> <p>5 justice.</p> <p>6 MR. SNELL: Obviously all the material</p> <p>7 is cited in her reports directly.</p> <p>8 MR. GRAND: Yes. I'm not questioning</p> <p>9 that, and just to be clear, I appreciate that</p> <p>10 there are articles cited in the text of the</p> <p>11 report itself, and it's very clear to me that</p> <p>12 you are relying on those articles.</p> <p>13 MR. SNELL: Okay.</p> <p>14 MR. GRAND: What's not clear to me is</p> <p>15 there is a lot of -- a lot of additional</p> <p>16 materials in the supplemental reliance list,</p> <p>17 and I need to know what I need to be prepared</p> <p>18 for at trial.</p> <p>19 MR. SNELL: Let's go off the record</p> <p>20 for a second. Is that okay?</p> <p>21 MR. GRAND: Sure.</p> <p>22 THE VIDEOGRAPHER: The time is</p> <p>23 10:13 a.m., and we are going off the video</p> <p>24 record.</p> <p>25 (Discussion was had off the</p>
<p style="text-align: center;">Page 47</p> <p>1 that would be relevant to your opinion, correct?</p> <p>2 MR. SNELL: Form.</p> <p>3 A. I would certainly want to --</p> <p>4 MR. SNELL: Foundation. Go ahead.</p> <p>5 A. I would want to know what her current</p> <p>6 complaints are and, more importantly, what the exam</p> <p>7 finding are.</p> <p>8 Q. Right. To be fair, to render an opinion</p> <p>9 in this case, you would want to have the most</p> <p>10 up-to-date information available, correct?</p> <p>11 MR. SNELL: Objection, form.</p> <p>12 A. I would like to look at the up-to-date</p> <p>13 exam.</p> <p>14 Q. Me too.</p> <p>15 A. We are closing this set right now? I</p> <p>16 don't want to mess up the papers.</p> <p>17 Q. We are closing the reliance list.</p> <p>18 A. Okay.</p> <p>19 Q. I don't want to ask you any more</p> <p>20 questions about the reliance list. My</p> <p>21 understanding is you are going to look at it during</p> <p>22 the break and try to tell me what you think is</p> <p>23 relevant to your opinions.</p> <p>24 MR. SNELL: We will probably do that</p> <p>25 over a break at lunch because it might take a</p>	<p>1 record.)</p> <p>2 THE VIDEOGRAPHER: The time is</p> <p>3 10:17 a.m., and we are back on the video</p> <p>4 record.</p> <p>5 BY MR. GRAND:</p> <p>6 Q. Dr. Elser, I understand that you have</p> <p>7 brought your file with you today, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And as part of that you have brought us</p> <p>10 a thumb drive and seven DVDs or CD-ROMs with --</p> <p>11 seven CD-ROMs, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Does this constitute all of the medical</p> <p>14 literature and records or documents you will have</p> <p>15 reviewed for this case?</p> <p>16 MR. SNELL: I'm going to object to</p> <p>17 form. There is other stuff she brought, just</p> <p>18 so the record is clear, because the video is</p> <p>19 not showing all of the materials she brought.</p> <p>20 MR. GRAND: Okay.</p> <p>21 MR. SNELL: I just want it to be</p> <p>22 accurate. That's all.</p> <p>23 MR. GRAND: No. I want to understand</p> <p>24 what we need to be walking away from here with</p> <p>25 today, so...</p>

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<p>1 MR. SNELL: You are free to mark 2 everything, and I have no problem with it, and 3 I think that's why the doctor brought it, so 4 you would have fair notice on all of the stuff 5 she has reviewed and considered. I know it is 6 pretty voluminous, but I don't know any way 7 around that, to be honest with you.</p> <p>8 MR. GRAND: Okay.</p> <p>9 MR. SNELL: Sometimes your experts 10 just show up a thumb drive, sometimes they 11 have hard copies. I mean, I make judgments on 12 what I mark and don't mark, but I don't want 13 there to be, you know, some misrepresentation 14 that that's all she has looked at, because she 15 did bring some hard copy stuff here today that 16 may or may not be in that. That's all I am 17 trying to say.</p> <p>18 BY MR. GRAND:</p> <p>19 Q. Doctor, I'm trying to identify what 20 materials you reviewed and relied on in preparing 21 your report, both of your reports.</p> <p>22 Beyond this thumb drive and these CDs, 23 what else is there?</p> <p>24 A. I believe -- I believe the thumb drive 25 is pretty comprehensive, but as Burt said, there</p>	<p>1 that's dated July 2nd, 2015. 2 Now, would this pertain to the TVT-O 3 case we were discussing earlier? 4 A. Yes. 5 Q. Would there be materials on this that 6 are relevant to your opinions in this case? 7 A. There could be. 8 Q. Another one marked "Ethicon Gynecare 9 Pelvic Mesh Litigation TVT-O." 10 Another one dated July 31st, 2015, "New 11 Prolift/POP studies." 12 Another one dated 7/31/15 that says 13 "Sling Long-Term Articles." 14 Another one dated June 2nd, 2015, 15 pertaining to the Edwards case. 16 And these are -- all of these CD-ROMs 17 are labeled Butler Snow. Is it fair to say these 18 were provided to you by Butler Snow? 19 A. Yes. 20 Q. Okay. And then we have additional 21 medical records and transcripts from the Corbet 22 case and this is dated August 25th, 2015? 23 A. Yes. 24 Q. Would it be fair to say you were working 25 on the supplemental report as early as August 25th,</p>
<p style="text-align: center;">Page 51</p> <p>1 may be some medical records and articles in these 2 binders that are not included on that thumb drive.</p> <p>3 MR. GRAND: Okay. I'm going to mark, 4 I guess -- I don't know how else to do it. I 5 don't know if I'm going to put a sticker on 6 this or not.</p> <p>7 MR. SNELL: That's what I usually do. 8 Just mark them in order so that they are 9 clear.</p> <p>10 MR. GRAND: I'm going to mark the 11 thumb drive and the --</p> <p>12 MR. SNELL: Why don't you mark the 13 thumb drive separate.</p> <p>14 MR. GRAND: All right. I'm going to 15 mark the CDs as Elser 5, and there is seven of 16 them, and I'm going to read out the titles of 17 them.</p> <p>18 One is "Ethicon Gynecare Pelvic Mesh 19 Litigation, Additional Medical Records & 20 Transcripts Corbet," and that appears to be 21 dated 8/25/15.</p> <p>22 Another one is marked "Corbet Ethicon 23 Gynecare Pelvic Mesh Litigation."</p> <p>24 Another one is marked "Ethicon 25 Gynecare Pelvic Mesh Litigation Edwards," and</p>	<p style="text-align: center;">Page 53</p> <p>1 2015? 2 MR. SNELL: Form. 3 A. No. I put the date on of when the 4 disk -- when I opened the envelope just to help me 5 keep track. I may not have even have looked at it 6 until I knew that we were going to do an additional 7 report.</p> <p>8 MR. GRAND: Okay. So those we are 9 going to let the court reporter -- can you 10 take and make a copy of it so we can get the 11 originals back to Dr. Elser? 12 THE REPORTER: I think so. 13 MR. GRAND: I'm going to mark as 14 Elser 6 --</p> <p>15 MR. SNELL: And can I just make a 16 request whenever they are copied, can the 17 cover that Mr. Grand read be reflected, can 18 they be separated maybe 7, you know, A, B, C, 19 D so that we know the different DVDs instead 20 of one large PDF file that is a cumulation of 21 all the electronic files on there. I don't 22 know if I'm being clear, but...</p> <p>23 MR. GRAND: Yeah, no. My feeling, I 24 would request if we could actually just get 25 burned copies of the CDs and then maybe just a</p>

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<p>1 PDF of the cover and the cover sheet. 2 MR. SNELL: Yeah, that's what I 3 meant. 4 MR. GRAND: I'm not suggesting we have 5 to print all these out. 6 I'm marking the thumb drive as 7 Elser 6, and let me just go off the record for 8 a second. 9 THE VIDEOGRAPHER: The time is 10 10:21 a.m., and we are going off the video 11 record. 12 (Recess taken, 10:21 - 10:36 a.m.) 13 (Said disks were marked Elser 14 Exhibits 5-A through Exhibit 5-G, 15 said thumb drive was marked as 16 Exhibit 6, and certain documents 17 were marked Exhibits 7 and 8, for 18 identification, as of 11/5/15.) 19 THE VIDEOGRAPHER: The time is 20 10:36 a.m., and we are back on the video 21 record. 22 MR. GRAND: Okay. So the record is 23 clear, the court reporter is going to take 24 Exhibit 5, which was the seven CD-ROMs. She 25 is going to copy them for us, and they will be</p>	<p>1 you looked at these articles? 2 A. No. 3 Q. What did you do on your own to 4 investigate or find out information about the 5 development of the TTV product and any early data 6 for that product? 7 A. You mean ever in my whole career? 8 Q. In connection with the Corbet case. 9 A. Well, some of -- 10 MR. SNELL: Form. Go ahead. 11 A. Well, certainly I have been practicing 12 since TTV first came to the U.S., so I have been 13 reading articles about TTV and its development for 14 many, many years, so some of those articles I had 15 already read and were already in my files and I 16 would have pulled for this case to re-review, and 17 some were provided to me, which I don't remember 18 when between August and now, but I read those 19 again. 20 Q. Okay. So, these are not -- these 21 articles you were already aware of. Did you 22 request that they be compiled for you this way, or 23 did the attorneys do that for you? 24 A. I did not request that. 25 Q. Okay. Let me just keep these together.</p>
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<p>1 labeled 5-A and 5-B, accordingly, as well as 2 Elser 6, which was the thumb drive. 3 BY MR. GRAND: 4 Q. During the break I went through your 5 file, and I am satisfied that the things contained 6 in the file are listed on the -- they are things we 7 are already aware of, such as deposition 8 transcripts and various articles, which I do not 9 need to mark or include at this point. 10 There is one thing that I did want to 11 ask you about, which I have marked as Elser 7, 12 which appears to be a small bound document called 13 TTV Development and Early Data. 14 A. Yes. 15 Q. Okay. Did you make this yourself? 16 A. No. 17 Q. Was this provided to you by Butler Snow? 18 A. Yes. 19 Q. And in fact, there is a letter in here 20 which I have marked as Elser 8, which is a letter 21 from a paralegal at Butler Snow transmitting this 22 to you for your review. It's dated August 27th, 23 2015. Do you see that? 24 A. Yes. 25 Q. So is August 27, 2015, the first time</p>	<p>1 What have you done to satisfy yourself 2 that you have a thorough collection of TTV 3 articles? 4 A. I'm not sure I understand. 5 Q. Well, this is a select group of 6 articles, correct? 7 A. Correct. 8 Q. You don't believe that this is every 9 article relating to the TTV development or early 10 data on the TTV, correct? 11 A. Oh, no. 12 Q. So, my question is, did you -- what did 13 you do to make sure you found other articles that 14 were not provided to you by attorneys? 15 A. Well, I do literature searches all the 16 time or I read journals as they come out every 17 month related to my field. 18 Q. We will just set these aside. 19 I want to circle back for a minute and 20 ask you some more questions about your practice. 21 What course of treatment do you currently recommend 22 for patients suffering from SUI? 23 MR. SNELL: Form. Go ahead. 24 A. Patients coming in with stress 25 incontinence, I always counsel them that their</p>

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<p style="text-align: center;">Page 58</p> <p>1 options are conservative to start with. They don't 2 need to treat it. They can -- if they are 3 overweight they can lose weight, which should help. 4 They can control their constipation, which affects 5 bladder function, and we can start with pelvic 6 exercise, and specifically my preference is 7 physical therapy, although not all patients have 8 access to that.</p> <p>9 Other options are to use a device like a 10 pessary or the new Impressa that's over the 11 counter. We have available to us then surgery for 12 treating the stress incontinence.</p> <p>13 Q. Okay. With respect to surgery, what 14 types of surgical options do you currently 15 recommend or discuss with your patients?</p> <p>16 A. My number one recommendation is a sling, 17 a midurethral sling, and there are some instances 18 where I will perform a Burch, and then also I did 19 not include periurethral injections of bulking 20 agents which are indicated for a subset of 21 patients.</p> <p>22 Q. So, just to be clear, your -- is your 23 sort of -- and understanding this may vary from 24 patient to patient and how they present to you, 25 your first-line recommendation would be more</p>	<p style="text-align: center;">Page 60</p> <p>1 prolapse, do you still do procedures involving mesh 2 to treat pelvic organ prolapse?</p> <p>3 A. Yes.</p> <p>4 Q. Is that -- do you typically do that 5 through the abdominal approach or transvaginal?</p> <p>6 A. If I use mesh, the majority are 7 abdominal, but I still employ vaginal mesh.</p> <p>8 Q. And which products do you currently use 9 to treat pelvic organ prolapse, mesh products?</p> <p>10 A. Most commonly I will use the Elevate, 11 which is an AMS product.</p> <p>12 Q. Do you use any Gynecare meshes to treat 13 pelvic organ prolapse currently?</p> <p>14 A. No.</p> <p>15 Q. Okay. I'm going to ask you some 16 questions about your first report, the July report.</p> <p>17 A. Okay. I think that's this one.</p> <p>18 Q. Towards the bottom of Page 1 you said, 19 you state, second-to-the-last line from the bottom, 20 "I am involved in teaching at the resident and 21 fellow level." Is that rounds, basically?</p> <p>22 A. We have had fellows in the office, 23 although currently I don't have one, and residents 24 work with us in the office and in the operating 25 room.</p>
<p style="text-align: center;">Page 59</p> <p>1 conservative treatments?</p> <p>2 A. Yes.</p> <p>3 Q. And then if you feel a surgical option 4 is needed, you would then go to a mesh sling?</p> <p>5 A. Yes.</p> <p>6 Q. And would you do that -- when you said 7 that the injections are limited to a certain subset 8 of patients, what patients are those better limited 9 to?</p> <p>10 A. Well, the bulking agents are indicated 11 for patients with intrinsic sphincteric deficiency, 12 which we abbreviate as ISD, and most specifically 13 those that don't have a hypermobile urethra, so a 14 fixed urethra; and it tends to not be a good option 15 for young women and it's more reserved for frail 16 elderly.</p> <p>17 Q. Other than a Burch procedure, are there 18 any types of, for lack of a better word, 19 traditional surgical options that you still employ?</p> <p>20 A. So, if you are asking about traditional 21 pubovesical slings, I don't perform those any more.</p> <p>22 Q. Okay.</p> <p>23 A. And I have done lots of them, but I 24 don't offer them.</p> <p>25 Q. And with respect to pelvic organ</p>	<p style="text-align: center;">Page 61</p> <p>1 Q. Okay. And you have already discussed 2 the slings that were -- the mesh slings that are 3 available at your hospital, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And when you do procedures at any -- at 6 the hospitals in which you work in, are you -- do 7 you have your own informed consents or do you rely 8 on the hospital's forms?</p> <p>9 A. When I'm working at the hospital or when 10 I'm consenting a patient for surgery?</p> <p>11 Q. Consenting a patient for surgery.</p> <p>12 A. Okay. So, I do have my own consents in 13 the office that I will go over with the patient 14 when we are talking about surgery, implanting it.</p> <p>15 Q. Do you have a different -- a different 16 consent form that you use for mesh slings?</p> <p>17 MR. SNELL: Form.</p> <p>18 A. I have a consent form for stress 19 incontinence surgery and I have a consent form for 20 prolapse surgery.</p> <p>21 Q. Would you have a copy of those in your 22 file?</p> <p>23 A. I don't think so.</p> <p>24 MR. GRAND: We would like to request a 25 copy of those consent forms, just whatever the</p>

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<p>1 template is.</p> <p>2 BY MR. GRAND:</p> <p>3 Q. And does your consent form vary from the</p> <p>4 hospital's? Is it different from the hospital's</p> <p>5 consent form?</p> <p>6 A. Yes.</p> <p>7 Q. The hospital's consent form tends to be</p> <p>8 a sort of catchall for anything that could go wrong</p> <p>9 in a procedure?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. The hospital's consent form is pretty</p> <p>12 vague and generic.</p> <p>13 Q. Do you think that's generally true of</p> <p>14 hospitals?</p> <p>15 A. Yes.</p> <p>16 Q. Now, looking at Page 2 of that report,</p> <p>17 you say, "In a typical week, I perform numerous</p> <p>18 incontinence and prolapse surgeries involving mesh</p> <p>19 and native tissue repairs, in addition to other</p> <p>20 surgeries"?</p> <p>21 A. Yes.</p> <p>22 Q. "I have also performed revision</p> <p>23 surgeries following incontinence and prolapse</p> <p>24 surgeries."</p> <p>25 Do you perform revision surgeries -- is</p>	<p>1 Q. And in fact, it may relate to other</p> <p>2 products besides the TTV Exact or Abbrevio, correct?</p> <p>3 A. Yes.</p> <p>4 Q. It could include Boston Scientific or</p> <p>5 AMS products as well, correct?</p> <p>6 A. Correct.</p> <p>7 Q. Skipping ahead to Page 30 of your</p> <p>8 report, which I believe is where you begin to</p> <p>9 address Kathleen Corbet specifically, on Page 31</p> <p>10 you note, "At her deposition, Mrs. Corbet testified</p> <p>11 she experienced symptoms of both urge and stress</p> <p>12 urinary incontinence leading up to her July 14th,</p> <p>13 2011 surgery."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. What symptoms of urge incontinence are</p> <p>17 you asserting that she testified to?</p> <p>18 A. I can look at her deposition with you,</p> <p>19 but I can't be more specific than that right now.</p> <p>20 This is what I assessed at the time I was looking</p> <p>21 at her deposition.</p> <p>22 Q. You say she also reported those symptoms</p> <p>23 on Dr. Harrell's intake questionnaire in April of</p> <p>24 2011, correct?</p> <p>25 A. Correct.</p>
<p>Page 63</p> <p>1 that generally on your own patients, or do you find</p> <p>2 that you are referred patients from other doctors</p> <p>3 for revision surgeries?</p> <p>4 A. Both.</p> <p>5 Q. Now, you said, "Our practice's sling</p> <p>6 revision rate for either exposure or incomplete</p> <p>7 bladder emptying is 4.5 percent." We discussed</p> <p>8 that earlier, correct?</p> <p>9 A. Correct.</p> <p>10 Q. Of that 4.5 percent, do you know, none</p> <p>11 of those, based on what you told me, none of those</p> <p>12 would relate to the TTV, correct?</p> <p>13 MR. SNELL: Form.</p> <p>14 Q. The TTV retropubic.</p> <p>15 A. I don't think that's true.</p> <p>16 Q. Well, you said you haven't used the TTV</p> <p>17 retropubic.</p> <p>18 A. Oh, I'm sorry. You mean not Exact.</p> <p>19 Most likely not, because I think at the time I</p> <p>20 looked at this data it was after we were already</p> <p>21 using Exact.</p> <p>22 Q. Okay. So this 4.5 percent would not</p> <p>23 relate to the TTV retropubic product, correct?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. I don't think so.</p>	<p>Page 65</p> <p>1 Q. What symptoms of urge incontinence did</p> <p>2 she have in Dr. Harrell's intake questionnaire?</p> <p>3 A. Well, again, do you want me to -- do you</p> <p>4 want to look at those?</p> <p>5 Q. Sure.</p> <p>6 A. Okay.</p> <p>7 I'm just not finding it right now, but</p> <p>8 I'll keep looking.</p> <p>9 Oh. The questionnaire is -- there is a</p> <p>10 questionnaire here with 18 questions, and it's</p> <p>11 number 12, "When you feel the desire to urinate, do</p> <p>12 you lose urine before you can get to the bathroom</p> <p>13 or toilet seat?"</p> <p>14 Q. Okay. So based on the response to that</p> <p>15 one question, you are of the opinion that she had</p> <p>16 urge incontinence prior to implant of her sling?</p> <p>17 A. Yes.</p> <p>18 MR. SNELL: Form. Go ahead.</p> <p>19 Q. And she did not have frequent urination</p> <p>20 during the night, correct?</p> <p>21 A. No. She said no at that time.</p> <p>22 Q. And she did not have frequent urination</p> <p>23 during the daytime hours either, did she?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. She said -- "Do you empty your bladder</p>

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<p>1 frequently?" She said "Sometimes."</p> <p>2 Q. I'm looking at question 14.</p> <p>3 A. I know. 14 she said no, but 15 is a</p> <p>4 sometimes.</p> <p>5 Q. And obviously Dr. Harrell examined her</p> <p>6 during that -- at that time, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And Dr. Harrell did not diagnose her</p> <p>9 with urge incontinence, correct?</p> <p>10 A. I will look at his first note.</p> <p>11 The impressions that he wrote down was</p> <p>12 cystocele and rectocele.</p> <p>13 Q. Keep going. And stress urinary</p> <p>14 incontinence, correct?</p> <p>15 A. Well, I'm sorry. Are we on a different</p> <p>16 page?</p> <p>17 Q. Well, you were reading the diagnosis.</p> <p>18 A. Yeah. This says chief complaints,</p> <p>19 complained of dropped bladder, new patient, and</p> <p>20 this is a typed --</p> <p>21 Q. Okay.</p> <p>22 A. -- note, and you might be looking at H&P</p> <p>23 before surgery.</p> <p>24 Q. Do you see chief complaint, dropped</p> <p>25 bladder and stress urinary incontinence?</p>	<p>1 What are you basing that on?</p> <p>2 A. Well, I wrote there that I took it from</p> <p>3 her deposition, so I would need to look at her</p> <p>4 deposition. Do you want me to pull that out?</p> <p>5 Q. No. I just want to know what your basis</p> <p>6 was.</p> <p>7 A. Okay.</p> <p>8 Q. And you've indicated Mrs. Corbet signed</p> <p>9 a hospital consent that warned of permanent injury</p> <p>10 and death, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And that's the same sort of vague</p> <p>13 consent form that the hospital uses?</p> <p>14 MR. SNELL: Objection, form.</p> <p>15 Q. You described it before as vague,</p> <p>16 correct?</p> <p>17 MR. SNELL: No. Objection,</p> <p>18 foundation, form.</p> <p>19 A. I described mine as vague, but as far as</p> <p>20 I know, that was just a hospital consent that would</p> <p>21 apply to any surgery.</p> <p>22 Q. Right. I guess that's my point. It was</p> <p>23 a hospital consent form that applied to any</p> <p>24 surgical procedure in the hospital, correct?</p> <p>25 A. Yes.</p>
<p>1 A. I think mine looks like an office note.</p> <p>2 It just says chief complaints, dropped bladder, new</p> <p>3 patient.</p> <p>4 Q. Okay.</p> <p>5 A. Oh, yes. Complaints of occasional SUI.</p> <p>6 I think we are on different pages.</p> <p>7 Q. That's fine. Have you seen any records</p> <p>8 from Dr. Harrell prior to her surgery indicating he</p> <p>9 had diagnosed her with -- have you reviewed any</p> <p>10 records from Dr. Harrell prior to her surgery,</p> <p>11 implant surgery, where he diagnosed her with urge</p> <p>12 incontinence?</p> <p>13 A. He didn't list that as a diagnosis.</p> <p>14 Q. And again, Dr. Harrell examined her at</p> <p>15 that time, correct?</p> <p>16 A. It appears so.</p> <p>17 Q. And you have never examined Mrs. Corbet,</p> <p>18 correct?</p> <p>19 A. No.</p> <p>20 Q. On Page 32 of your report, the last</p> <p>21 sentence on Page 31 leading into 32, you state,</p> <p>22 "Mrs. Corbet also testified that Dr. Harrell warned</p> <p>23 her of a risk of dyspareunia, although there is a</p> <p>24 dispute as to whether he described it as</p> <p>25 temporary."</p>	<p>1 Q. There is always a potential for</p> <p>2 permanent injury and death when you undergo a</p> <p>3 surgical procedure, correct?</p> <p>4 A. Yes.</p> <p>5 Q. If you go down a little bit further, the</p> <p>6 fourth sentence from the bottom on Page 32, you see</p> <p>7 you indicated by December 2011 more than five</p> <p>8 months after surgery the patient felt better?</p> <p>9 A. Yes.</p> <p>10 Q. Is it your opinion that her symptoms she</p> <p>11 had following surgery had resolved by December</p> <p>12 2011?</p> <p>13 A. That's how it appeared.</p> <p>14 And if I could clarify, this was she was</p> <p>15 feeling pressure from this blood clot, and I</p> <p>16 believe that's what we were referring to here.</p> <p>17 Q. Okay. So you are not suggesting that</p> <p>18 she wasn't experiencing other symptoms at that</p> <p>19 time?</p> <p>20 A. Right.</p> <p>21 Q. So you are just referring to the</p> <p>22 hematoma?</p> <p>23 A. Right. She was being followed for a</p> <p>24 hematoma.</p> <p>25 Q. But you saw prior to that there were</p>

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<p style="text-align: right;">Page 70</p> <p>1 complaint of dyspareunia, correct?</p> <p>2 MR. SNELL: Form.</p> <p>3 A. Yes.</p> <p>4 Q. And those complaints continued into the</p> <p>5 following year, correct?</p> <p>6 A. Yes, yes.</p> <p>7 Q. In fact, you wrote May 2012, ten months</p> <p>8 postoperatively, Mrs. Corbet continued to have</p> <p>9 complaints, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And did you review the pathology from</p> <p>12 the mesh revision?</p> <p>13 A. I had seen the pathology report.</p> <p>14 Q. And just to be clear, she was diagnosed</p> <p>15 with the mesh exposure and it was removed in</p> <p>16 January of 2013, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And you know the pathology noted a</p> <p>19 chronic inflammation and foreign body giant cell</p> <p>20 reaction, correct?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. Yes.</p> <p>23 Q. Is it your understanding that the</p> <p>24 foreign body reaction that takes place once a mesh</p> <p>25 is implanted is transient or a -- or chronic</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. Okay. I just want to make sure I wasn't</p> <p>2 -- I was trying to determine whether that was a</p> <p>3 criticism of the treating doctor to treat her this</p> <p>4 way?</p> <p>5 A. No.</p> <p>6 Q. Is that how you would have treated her?</p> <p>7 A. It's an option.</p> <p>8 Q. Is that how you would have treated her?</p> <p>9 A. I personally don't perform InterStim.</p> <p>10 Some patients I refer to a partner for InterStim,</p> <p>11 but my first line may have been different.</p> <p>12 Q. What would your first line have been?</p> <p>13 A. I would work more on the physical</p> <p>14 therapy and neuromodulation. That's less invasive.</p> <p>15 Q. And you said you sometimes performed</p> <p>16 revisions of slings?</p> <p>17 A. Yes. Thank you. I caught that, yeah.</p> <p>18 Q. How many revisions do you perform a</p> <p>19 year, would you say, sling revisions?</p> <p>20 A. I haven't counted that recently, so it</p> <p>21 would be a guess, but, you know, maybe a couple a</p> <p>22 month, and it's getting less and less, we are</p> <p>23 seeing.</p> <p>24 Q. I want to ask you some questions about</p> <p>25 Mrs. Corbet's hematoma. Is it your opinion that</p>
<p style="text-align: right;">Page 71</p> <p>1 ongoing reaction?</p> <p>2 A. I believe it can be chronic.</p> <p>3 Q. You believe it can be chronic. And what</p> <p>4 factors do you think affects whether it's chronic</p> <p>5 or transient?</p> <p>6 A. I really don't know.</p> <p>7 Q. If you go ahead to Page 34 in your</p> <p>8 report, at the very top you wrote, "Despite the</p> <p>9 findings of stress incontinence and elevated</p> <p>10 bladder capacity with no DO, even at 780</p> <p>11 millimeters bladder filling, the patient was</p> <p>12 randomized to an invasive procedure for OAB and</p> <p>13 underwent a two-stage InterStim implantation."</p> <p>14 Are you suggesting that this was an</p> <p>15 incorrect course of treatment?</p> <p>16 A. Excuse me. No. I just -- having been</p> <p>17 involved in other studies regarding urge</p> <p>18 incontinence, usually patients with OAB have a</p> <p>19 small bladder capacity. So, I was just surprised</p> <p>20 that the study criteria allowed a patient with a</p> <p>21 maximum capacity of 800, which is very high, to be</p> <p>22 in the study.</p> <p>23 Q. Okay. So you --</p> <p>24 A. I'm not saying that someone with sensory</p> <p>25 urgency doesn't benefit from InterStim.</p>	<p style="text-align: right;">Page 73</p> <p>1 the hematoma was caused by her prolapse repair as</p> <p>2 opposed to the mesh, as opposed to the mesh sling?</p> <p>3 A. We don't know if it was caused by the</p> <p>4 prolapse repair or the sling procedure.</p> <p>5 Q. So you don't have an opinion either way?</p> <p>6 MR. SNELL: Form.</p> <p>7 A. It could be from either one. No one can</p> <p>8 know for sure.</p> <p>9 Q. And then you state on the next page,</p> <p>10 "The TTV IFU adequately warns of the risk of</p> <p>11 hematoma" --</p> <p>12 A. I'm sorry. What's the next page?</p> <p>13 Q. I'm sorry. Page 35, the last sentence</p> <p>14 right before the urge incontinence section.</p> <p>15 A. Yes.</p> <p>16 Q. You said, "The TTV IFU adequately warns</p> <p>17 of the risk of hematoma by warning of punctures or</p> <p>18 lacerations to vessels."</p> <p>19 A. Yes.</p> <p>20 Q. And you are referring to the IFU that</p> <p>21 was in place at the time of her surgery or the</p> <p>22 current IFU for the TTV?</p> <p>23 A. It would have been the one in place at</p> <p>24 the time of her surgery.</p> <p>25 Q. And you believe the warning of the risk</p>

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<p>1 of puncturing or laceration is going to be the same 2 thing as warning of the risk of hematoma? 3 A. I believe any surgeon doing an 4 incontinence or prolapse surgery knows that when 5 operating on anybody you can create bleeding or 6 hematoma, and certainly you know if there is a 7 vessel injury there can be blood loss at the time 8 of surgery or a hematoma that collects. 9 MR. GRAND: Move to strike as 10 nonresponsive. 11 BY MR. GRAND: 12 Q. Do you believe that warning of the risk 13 of hematoma is the same as warning of the risk of 14 punctures or lacerations to vessels? 15 MR. SNELL: Form. 16 A. I believe it's adequate warning. 17 Q. Have you reviewed the new TVT label? 18 A. The new label, the new IFU? 19 Q. Yes, yes. 20 A. I reviewed one in the OR yesterday that 21 was a 2014, but I understand there is an even newer 22 one. 23 Q. You haven't seen the new one yet? 24 A. No. 25 MR. GRAND: I'm going to mark -- what</p>	<p>1 THE WITNESS: I said I can read Greek, 2 but you want the English, right? 3 BY MR. GRAND: 4 Q. Yes. I'm going to ask you to turn to 5 Page 5 of each one. 6 A. Okay. 7 Okay. 8 Q. So, I want to call your attention to the 9 adverse reaction section. 10 A. Okay. 11 Q. So you will see that -- 12 A. The big one is the new one, right? 13 Q. Yes, the big one is the new one. 14 A. All right. 15 Q. And if you look, they still -- if you 16 look at the first bullet point under the adverse 17 reactions, it says, "Punctures or lacerations of 18 vessels, nerves, structures or organs, including 19 the bladder, urethra or bowel, may occur and may 20 require surgical repair." 21 That is largely the same as in the 22 original? 23 A. Right. 24 Q. I think the only difference is they 25 added in the word "structures" as well as</p>
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<p>1 are we up to? 9. 2 THE WITNESS: I might need a 3 magnifying glass. 4 MR. GRAND: I apologize. This is the 5 way I got it. 6 I'm going to mark as Elser 9 the TVT 7 label that was in place at the time of 8 Mrs. Corbet's implant. 9 THE WITNESS: I have to lean back a 10 little bit, okay? Am I still in camera range? 11 THE VIDEOGRAPHER: Oh, yes. 12 MR. GRAND: And I'm going to mark as 13 No. 10 the label that was revised in January 14 of this year. 15 (Elser Exhibits 9 and 10 were marked 16 for identification as of 11/5/15.) 17 THE WITNESS: Thank you. 18 MR. GRAND: Burt, need copies? 19 MR. SNELL: Yes, please. 20 THE WITNESS: That one is a lot 21 bigger. 22 MR. GRAND: Yes. That one is easier to 23 read. 24 THE WITNESS: I can read Greek -- 25 MR. GRAND: What?</p>	<p>1 "urethra." But you see further down they also 2 included "bleeding, including hemorrhage and 3 hematoma," if you go several bullet points down in 4 the new label. 5 A. Yes. 6 Q. In fact, there is multiple reactions 7 that have been added to this new label that are not 8 listed in the first label, such as do you see 9 "acute and chronic pain"? 10 A. Yes. 11 Q. Do you see "voiding dysfunction"? 12 A. Yes. 13 Q. Do you see "pain with intercourse," 14 which in some patients may not resolve"? 15 A. Yes. 16 Q. Do you see "neuromuscular problems 17 including acute and/or chronic pain in the groin, 18 thigh, leg, pelvic and/or abdominal area may 19 occur"? 20 A. Yes. 21 Q. Do you see "recurrence of incontinence"? 22 A. Yes. 23 Q. And you already said bleeding, including 24 hemorrhage or hematoma. 25 "One or more revision surgeries may be</p>

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<p style="text-align: right;">Page 78</p> <p>1 necessary to treat these adverse reactions"?</p> <p>2 A. Yes.</p> <p>3 Q. "Additionally, the Prolene mesh is a</p> <p>4 permanent implant that integrates into the tissue.</p> <p>5 In cases in which the Prolene mesh needs to be</p> <p>6 removed in part or whole, significant dissection</p> <p>7 may be required"?</p> <p>8 A. Yes.</p> <p>9 Q. And by that, that's not necessarily a</p> <p>10 snip in the doctor's office, correct, when they are</p> <p>11 talking about a significant dissection?</p> <p>12 MR. SNELL: Form.</p> <p>13 A. If it has to be removed in its whole,</p> <p>14 right, that would not be done in the office.</p> <p>15 Q. That's not a -- that's a much more</p> <p>16 invasive procedure, correct?</p> <p>17 A. Right.</p> <p>18 MR. SNELL: Form.</p> <p>19 Q. And it's generally going to have to be</p> <p>20 done under general anesthesia?</p> <p>21 A. Under anesthesia.</p> <p>22 Q. Do you see under other adverse reactions</p> <p>23 they have added a whole other section there? Do</p> <p>24 you see that?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. SNELL: Form.</p> <p>2 A. You are asking if it is temporary or if</p> <p>3 it says it is temporary?</p> <p>4 Q. I'm asking if the risks associated with</p> <p>5 the surgery tend to be temporary conditions rather</p> <p>6 than permanent conditions.</p> <p>7 MR. SNELL: Form. I don't know what</p> <p>8 you mean by "the surgery." That's my form.</p> <p>9 MR. GRAND: You don't know what</p> <p>10 surgery we are talking about?</p> <p>11 MR. SNELL: Are you talking about a</p> <p>12 straight TTVT or are you talking about --</p> <p>13 MR. GRAND: I'm talking about -- well,</p> <p>14 she's -- strike that. Let's just go back.</p> <p>15 MR. SNELL: That's my form. If you</p> <p>16 want to correct it, correct it. I don't care.</p> <p>17 MR. GRAND: I will strike the</p> <p>18 question.</p> <p>19 BY MR. GRAND:</p> <p>20 Q. Is it your opinion that with the</p> <p>21 exception of exposure all the risks listed in this</p> <p>22 new label under adverse reactions, the ones we have</p> <p>23 just been discussing, are -- are the same risk that</p> <p>24 would be in any pelvic floor surgery?</p> <p>25 A. Okay. So, foreign body response, you</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. It has urge incontinence. That wasn't</p> <p>2 in the original label either, correct?</p> <p>3 A. Correct.</p> <p>4 Q. Urinary frequency, urinary retention,</p> <p>5 adhesion formation, atypical vaginal discharge, and</p> <p>6 exposed mesh may cause pain or discomfort to the</p> <p>7 patient's partner during intercourse. That wasn't</p> <p>8 in the original label, correct?</p> <p>9 A. No.</p> <p>10 Q. Do you think that the new label gives</p> <p>11 better warnings than the original label?</p> <p>12 MR. SNELL: Form.</p> <p>13 A. It gives more warnings, but taking that,</p> <p>14 really, you know, what's unique about using mesh</p> <p>15 versus doing surgery without mesh is the exposure,</p> <p>16 erosion. So, being a surgeon, most of these are</p> <p>17 generic to surgery. So, it gives more warnings,</p> <p>18 more specific warnings, but it's not -- these are</p> <p>19 not especially enlightening.</p> <p>20 Q. A lot of risks associated with the</p> <p>21 surgery are temporary reactions, correct?</p> <p>22 A. Like bleeding, you would hope that would</p> <p>23 be temporary, yeah.</p> <p>24 Q. Well, even -- even pain with</p> <p>25 intercourse?</p>	<p style="text-align: right;">Page 81</p> <p>1 could have permanent sutures with foreign body</p> <p>2 response, and that could happen with any prolapse</p> <p>3 surgery. I think the only other thing here unique</p> <p>4 to sling versus surgery without using mesh is that</p> <p>5 the mesh might need to be removed in its whole.</p> <p>6 But otherwise, any surgery for</p> <p>7 incontinence can have voiding dysfunction, acute or</p> <p>8 chronic pain, dyspareunia or apareunia, hemorrhage,</p> <p>9 bleeding, recurrence of incontinence. So, these</p> <p>10 are pretty nonspecific.</p> <p>11 Q. Exposed mesh that may cause pain or</p> <p>12 discomfort to the patient's partner during</p> <p>13 intercourse, that's certainly not with every</p> <p>14 surgery, right?</p> <p>15 A. No, but permanent sutures had the same</p> <p>16 risk, so sometimes surgeries were done with</p> <p>17 permanent sutures in the vagina, and that also had</p> <p>18 the risk.</p> <p>19 Q. Is it your testimony that the sutures</p> <p>20 that may have been done in a more traditional</p> <p>21 repair carry the same risk of a foreign body</p> <p>22 response as a large piece of mesh?</p> <p>23 MR. SNELL: Form.</p> <p>24 A. I wouldn't call a sling a large piece of</p> <p>25 mesh, but I don't know if it has the same foreign</p>

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<p>1 body response. I've not looked at the pathology. 2 But certainly clinically we have patients that come 3 back with granulation tissue, chronic inflammation, 4 and need a couple procedures to get rid of those 5 polyps or granulation tissue, bleeding with 6 intercourse because of those permanent sutures 7 that's in the vaginal wall.</p> <p>8 Q. Relative to sutures, there is a lot more 9 mesh in a sling than in a suture, correct?</p> <p>10 MR. SNELL: Form.</p> <p>11 A. There is more mesh in a sling.</p> <p>12 Q. So if a patient is suffering from a 13 foreign body response, they are going to have a 14 greater foreign body response to the sling than to 15 a suture, correct?</p> <p>16 MR. SNELL: Form, foundation.</p> <p>17 A. There is more mesh material to react. 18 I've never thought of it, like said clinically a 19 patient is suffering from a foreign body response. 20 It's just an unusual phrase.</p> <p>21 Q. Have you ever seen materials provided to 22 doctors for TVT products that suggest that the 23 irritation is just transient as opposed to ongoing?</p> <p>24 A. The irritation?</p> <p>25 Q. The foreign body response.</p>	<p>1 MR. SNELL: Form.</p> <p>2 A. I don't have that information.</p> <p>3 Q. You haven't studied that issue?</p> <p>4 A. Right.</p> <p>5 Q. Have you seen studies showing an 6 increase in urge incontinence following mesh -- the 7 implantation of a mesh sling as high as 25 percent 8 of patients?</p> <p>9 A. Yes.</p> <p>10 Q. Put the label aside for now. 11 So, you don't have any opinion as to 12 whether the new label is a more -- is a more 13 adequate label than the label that was in place at 14 the time Dr. Harrell implanted the -- I mean, 15 sorry -- Dr. Harrell implanted the sling in 16 Mrs. Corbet?</p> <p>17 A. No. The IFU is the IFU, and as a 18 surgeon, we don't rely on this to know what could 19 go wrong with pelvic surgery. We want to know 20 specifics to the product. So, again, there is very 21 little here specific about the product that 22 somebody implanting slings would not already know 23 where it's covered. We know mesh exposure can 24 happen. We know patients can have pain. We know 25 that a sling may need to be removed partially or in</p>
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<p>1 A. I don't recall.</p> <p>2 Q. But it's your view that the foreign body 3 response can be ongoing and chronic, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it would certainly provide more 6 information to doctors to indicate that it could be 7 ongoing and chronic rather than just transient, 8 correct?</p> <p>9 MR. SNELL: Form, foundation.</p> <p>10 A. I don't understand. Can you say that 11 again?</p> <p>12 Q. It would be better to provide doctors 13 with information that tells them it can be ongoing 14 and chronic rather than it would just be transient 15 or temporary, correct?</p> <p>16 MR. SNELL: Same objection, form, 17 foundation.</p> <p>18 A. No, because what I was thinking, it 19 could be chronic. I don't know. We don't take all 20 our slings and bring them out of patients and 21 analyze and say is there any foreign body response 22 microscopically. I don't know if it goes on for a 23 long time or transient.</p> <p>24 Q. So you don't hold yourself out as an 25 expert in that area, correct?</p>	<p>1 whole.</p> <p>2 Q. You are aware Dr. Harrell testified that 3 he didn't know of many of these issues, correct?</p> <p>4 MR. SNELL: Form, foundation.</p> <p>5 A. I need to look at his testimony again.</p> <p>6 Q. Did you read his testimony?</p> <p>7 A. I did, yes, absolutely. I don't 8 remember that specific answer.</p> <p>9 Q. Were you aware that he testified that 10 had he known about the foreign -- the chronic 11 foreign body reaction he would not have implanted 12 the sling?</p> <p>13 A. No, I don't remember that.</p> <p>14 Q. You are not -- your opinions about what 15 surgeons know don't extend to Dr. Harrell, do they?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. Meaning I don't know what he knows?</p> <p>18 Q. Meaning you don't know what risks 19 Dr. Harrell believes were attendant to the mesh at 20 the time he implanted it in Mrs. Corbet?</p> <p>21 A. I don't know exactly what he thought the 22 risks were, but again, someone doing incontinence 23 surgery and prolapse surgery knows the risks -- 24 should know the risks of pelvic surgery.</p> <p>25 Q. Is that just an opinion you are holding</p>

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<p>1 for all, all surgeons?</p> <p>2 A. Yes.</p> <p>3 Q. So, in your opinion, what risks should</p> <p>4 have been known to Dr. Harrell at the time he</p> <p>5 implanted the TTV retropubic in Mrs. Corbet?</p> <p>6 A. That's pretty vague. Did you want me to</p> <p>7 talk about all risks of surgery, about anything</p> <p>8 that could and might happen with the sling?</p> <p>9 MR. GRAND: Strike that question.</p> <p>10 BY MR. GRAND:</p> <p>11 Q. Getting back to your report -- I'm</p> <p>12 sorry, actually. You wrote in your report on</p> <p>13 Page 36 that the IFU adequately warned of the risk</p> <p>14 of urge incontinence by warning surgeons that with</p> <p>15 other procedures detrusor instability can occur.</p> <p>16 A. Okay.</p> <p>17 Q. And then it says to minimize this risk,</p> <p>18 make sure that the tape tension -- the tape is</p> <p>19 placed tension-free in the midurethral position.</p> <p>20 Do you see that in the label?</p> <p>21 A. No. What page are you on?</p> <p>22 Q. I'm sorry. Above the adverse event</p> <p>23 section.</p> <p>24 A. Okay. You've got highlights. I don't</p> <p>25 have that advantage. Okay.</p>	<p>1 in, much of this would be knowledge to them without</p> <p>2 it being specifically in the IFU.</p> <p>3 Q. Well, if for some reason a doctor didn't</p> <p>4 receive lots of training...</p> <p>5 MR. SNELL: Is there a question?</p> <p>6 MR. GRAND: I was about to finish. I</p> <p>7 thought you were about to make an objection.</p> <p>8 MR. SNELL: Well, I am going to.</p> <p>9 BY MR. GRAND:</p> <p>10 Q. Okay. Do you know how much training</p> <p>11 Dr. Harrell received?</p> <p>12 A. No.</p> <p>13 Q. Okay. Were you aware that Ethicon</p> <p>14 suspended its training on the TTV after a certain</p> <p>15 period of time following launch?</p> <p>16 MR. SNELL: Objection, foundation.</p> <p>17 A. Suspended? I did know they were not</p> <p>18 offering training programs for a while.</p> <p>19 Q. There certainly is no harm in having</p> <p>20 more information in the IFU, correct?</p> <p>21 A. No. I don't see any harm in it.</p> <p>22 Q. So you don't disagree with -- do you</p> <p>23 disagree with any of the changes they made to the</p> <p>24 label?</p> <p>25 A. No.</p>
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<p>1 Q. It's like three bullet points up.</p> <p>2 A. Yes.</p> <p>3 THE VIDEOGRAPHER: Excuse me,</p> <p>4 counselor. We have to end this tape now.</p> <p>5 MR. GRAND: We need to switch the tape</p> <p>6 out.</p> <p>7 THE VIDEOGRAPHER: The time is</p> <p>8 11:25 a.m. This is the end of Tape 1, and we</p> <p>9 are going off the video record.</p> <p>10 (Recess taken, 11:25 - 11:31 a.m.)</p> <p>11 THE VIDEOGRAPHER: The time is</p> <p>12 11:31 a.m. This is the beginning of Tape 2,</p> <p>13 and we are back on the video record.</p> <p>14 BY MR. GRAND:</p> <p>15 Q. Just to be clear, with respect to the</p> <p>16 new label versus the label that was in place at the</p> <p>17 time of Mrs. Corbet's implantation, you think the</p> <p>18 original label is just as adequate as the current</p> <p>19 label --</p> <p>20 A. I do.</p> <p>21 Q. -- in terms of giving doctors</p> <p>22 information?</p> <p>23 A. Well, because this should not be the</p> <p>24 only source of information, so I think if a doctor</p> <p>25 is doing a sling and putting a permanent implant</p>	<p>1 Q. I mean, ultimately you would like</p> <p>2 doctors to have as much information as they can</p> <p>3 about a product, correct?</p> <p>4 MR. SNELL: Form.</p> <p>5 A. I want them, right, to understand about</p> <p>6 the surgery they are doing before they do the</p> <p>7 surgery. I just don't know that IFU is the place</p> <p>8 where physicians should get their education.</p> <p>9 Q. IFU is not the sole source of</p> <p>10 information about the product, correct?</p> <p>11 A. Correct.</p> <p>12 Q. Getting back to your original report, if</p> <p>13 we could draw your attention to Page 36, with</p> <p>14 respect to constipation, is it your opinion that</p> <p>15 Mrs. Corbet suffered from chronic constipation</p> <p>16 prior to her implant?</p> <p>17 A. Yes.</p> <p>18 Q. And what about post implant?</p> <p>19 A. I have to look at her records after the</p> <p>20 implant on the constipation. Do you want me to?</p> <p>21 Q. Yeah, sure.</p> <p>22 A. Okay. When she sees Dr. Smith</p> <p>23 January 31st she reports constipation.</p> <p>24 Q. And you know how her constipation was</p> <p>25 being managed at that time?</p>

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<p>1 A. She was taking Colace.</p> <p>2 Q. And have you seen visit notes where she</p> <p>3 says she is doing fine with the stool softener?</p> <p>4 A. I don't recall. I would have to look.</p> <p>5 Q. Is it your opinion that the constipation</p> <p>6 is a causal factor to her urge incontinence?</p> <p>7 A. It can be, yes. It can contribute</p> <p>8 significantly.</p> <p>9 Q. Is it your opinion that it contributed</p> <p>10 significantly in this case?</p> <p>11 A. It is very likely to be part of the</p> <p>12 problem.</p> <p>13 Q. Is it your opinion that the constipation</p> <p>14 has contributed to her dyspareunia?</p> <p>15 A. It can as well.</p> <p>16 Q. Is it your opinion that it has</p> <p>17 contributed to the dyspareunia in this case?</p> <p>18 A. It's very likely to be a part of the</p> <p>19 cause of the dyspareunia.</p> <p>20 Q. And what are you basing that on?</p> <p>21 A. Based on the patients I take care of</p> <p>22 with constipation and status post the posterior</p> <p>23 repair as well as literature, which including the</p> <p>24 one I put in the report, which was just a patient</p> <p>25 education brochure talking about constipation.</p>	<p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 A. This is really a ground-breaking study</p> <p>4 because up until that time everyone thought if you</p> <p>5 have constipation, the posterior repair, the</p> <p>6 posterior colporrhaphy fixes your constipation when</p> <p>7 you fix a rectocele, and this is really the first</p> <p>8 study that shows that's wrong. You have to treat</p> <p>9 constipation separately because it is a cause of</p> <p>10 pain and it's related to pain and sexual</p> <p>11 dysfunction.</p> <p>12 Q. Okay. But the surgery you cite</p> <p>13 doesn't -- doesn't state that the constipation is</p> <p>14 causing sexual dysfunction; it's that the prior</p> <p>15 surgery causes sexual dysfunction?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. Right. I'm saying the constipation can</p> <p>18 lead to pelvic pain which can cause sexual</p> <p>19 dysfunction.</p> <p>20 Q. Okay. I'm asking you what are you</p> <p>21 basing that on.</p> <p>22 A. I'm basing it on my experience, as well</p> <p>23 as if you carry on down, there is more examples of</p> <p>24 some of that literature that supports that, which</p> <p>25 is Dr. Butrick talking about the pelvic floor</p>
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<p>1 Q. Okay. Just to be clear, the dyspareunia</p> <p>2 in the brochure is a complication related to</p> <p>3 posterior vaginal wall repair, correct?</p> <p>4 A. Okay. Yes.</p> <p>5 Q. It's not relating it to constipation,</p> <p>6 correct?</p> <p>7 A. Right. They just warn about</p> <p>8 constipation there.</p> <p>9 Q. Okay.</p> <p>10 A. But yes, if you go on to the next page</p> <p>11 where I talk about pelvic floor hypertonicity,</p> <p>12 which can be related to -- causally to</p> <p>13 constipation, it frequently causes dyspareunia.</p> <p>14 Q. If we go on to Page 38.</p> <p>15 I just want to -- so, just to go back to</p> <p>16 your constipation section in the report, you cite</p> <p>17 -- on Page 37 you cite the Kahn study from 1997?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. That study linked that the</p> <p>20 surgery, which was a colporrhaphy -- did I get that</p> <p>21 correct?</p> <p>22 A. Yeah. That was good.</p> <p>23 Q. I have a hard time with that one.</p> <p>24 -- that the colporrhaphy may worsen or</p> <p>25 cause constipation, correct?</p>	<p>1 hypertonicity, which it's all a vicious cycle. It</p> <p>2 can be caused by constipation, it can be caused by</p> <p>3 a posterior colporrhaphy, but they are all</p> <p>4 connected.</p> <p>5 Q. Are you aware of any studies that link,</p> <p>6 that demonstrate a causal association between</p> <p>7 constipation and dyspareunia?</p> <p>8 A. I don't have those cited here, but I</p> <p>9 could probably find something.</p> <p>10 Q. And you didn't rely on such studies for</p> <p>11 your report, correct?</p> <p>12 A. I'm relying on my experience.</p> <p>13 Q. Your experience, and that's your</p> <p>14 experience with your patients, correct?</p> <p>15 A. Right, and reading about the issue, so</p> <p>16 I'm sure I've also read about it.</p> <p>17 Q. If we can proceed ahead to the section</p> <p>18 on dyspareunia beginning on Page 38. You cite the</p> <p>19 Pauls report from 2007?</p> <p>20 A. Yes.</p> <p>21 Q. That report examined women six months</p> <p>22 postoperatively?</p> <p>23 A. Yes.</p> <p>24 Q. You don't think that's an indicator of</p> <p>25 any potential long-term dyspareunia, correct?</p>

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<p>1 A. It can be.</p> <p>2 Q. But the study only looked at people six</p> <p>3 months postoperatively, correct?</p> <p>4 A. Correct.</p> <p>5 Q. You wouldn't consider that a long-term</p> <p>6 study, correct?</p> <p>7 A. Oh, no. I'm saying it could be</p> <p>8 long-term because of my experience with patients</p> <p>9 that when they have the surgery, they can have</p> <p>10 chronic pain afterwards, whether or not they have</p> <p>11 an incontinence procedure.</p> <p>12 Q. For purposes of looking at potential</p> <p>13 adverse effects of mesh implantation, what would</p> <p>14 you consider to be a long-term study?</p> <p>15 A. Long-term study. So, you know, when I</p> <p>16 was a fellow, long-term was more than six weeks, so</p> <p>17 we were really excited to get three-month data or</p> <p>18 six-month data, and the practice of our medicine in</p> <p>19 urogynecology has really changed over the last</p> <p>20 couple of decades. So, now we want to really get</p> <p>21 one-year data, but five-year data makes us feel</p> <p>22 much more comfortable that we know the long-term</p> <p>23 effects.</p> <p>24 Q. Is it your opinion that Mrs. Corbet</p> <p>25 suffered from dyspareunia prior to her implant?</p>	<p>1 Q. There were still questions on here</p> <p>2 regarding pain.</p> <p>3 A. I know we just looked at it. Here we</p> <p>4 go. No, they don't have any question about it</p> <p>5 here. Okay. So, the answer is no.</p> <p>6 Q. On Page 41, your comments on the case,</p> <p>7 towards the bottom you say, "In my opinion TTVT was</p> <p>8 a good option for Mrs. Corbet."</p> <p>9 A. Yes.</p> <p>10 Q. What other options would have been</p> <p>11 available to Mrs. Corbet? Strike that.</p> <p>12 Is it your opinion that the TTVT should</p> <p>13 have been the sort of first-line option for</p> <p>14 Mrs. Corbet based on her presentation?</p> <p>15 A. Well, that's the decision made between a</p> <p>16 patient and her physician.</p> <p>17 Q. I understand that. I'm asking your</p> <p>18 opinion.</p> <p>19 A. She had stress incontinence and she is</p> <p>20 seeking surgical treatment of prolapse and is</p> <p>21 c counseled and accepts to have an incontinence</p> <p>22 procedure done at the same time; I have no problem</p> <p>23 with that.</p> <p>24 Q. So you are not suggesting Dr. Harrell --</p> <p>25 you are not of the opinion that Dr. Harrell did</p>
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<p>1 A. I did not state that, but let me take a</p> <p>2 look.</p> <p>3 Q. I didn't think you did either. I'm just</p> <p>4 trying to make sure I understand.</p> <p>5 A. Okay. Do you want me to keep looking</p> <p>6 or...</p> <p>7 Q. If you can tell me that that's not what</p> <p>8 you -- that's not your opinion, that's fine.</p> <p>9 A. Okay.</p> <p>10 Q. Then you don't need to look at anything.</p> <p>11 Are you still looking?</p> <p>12 A. Yeah, but I'm listening.</p> <p>13 Q. Okay. I don't want --</p> <p>14 A. I'm a multi-tasker.</p> <p>15 Q. If you don't have a need to look for it,</p> <p>16 that's fine. I just --</p> <p>17 A. I'm curious. I want to look for it.</p> <p>18 Q. Are you going to supplement your report</p> <p>19 right now?</p> <p>20 A. Well...</p> <p>21 I just want to look at that one</p> <p>22 questionnaire we addressed a couple minutes ago.</p> <p>23 Q. Oh, okay.</p> <p>24 A. That was where we talked about the urge</p> <p>25 incontinence.</p>	<p>1 anything wrong by implanting a Prolift at that</p> <p>2 time?</p> <p>3 MR. SNELL: Form. There was no</p> <p>4 Prolift implanted.</p> <p>5 MR. GRAND: I'm sorry. Strike that.</p> <p>6 BY MR. GRAND:</p> <p>7 Q. You are not suggesting that Dr. Harrell</p> <p>8 did anything wrong by implanting a TTVT retropubic</p> <p>9 at that time as opposed to an alternative</p> <p>10 treatment?</p> <p>11 A. Right.</p> <p>12 Q. Mrs. Corbet's hematoma and the mesh --</p> <p>13 her mesh exposure are both on the left side,</p> <p>14 correct?</p> <p>15 A. Right, yes, correct.</p> <p>16 Q. And your understanding is that the left</p> <p>17 arm and a portion of the sling were removed but</p> <p>18 that the right arm remained in place, correct?</p> <p>19 MR. SNELL: Foundation, form. There</p> <p>20 is no arm in the sling. I think you are</p> <p>21 confusing Prolift again.</p> <p>22 MR. GRAND: I'm going by the revision</p> <p>23 record. Let's see.</p> <p>24 MR. SNELL: Okay.</p> <p>25 MR. GRAND: "Arm" may not be the right</p>

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<p>1 word. 2 MR. SNELL: Form and foundation. 3 BY MR. GRAND: 4 Q. Is it your understanding that the 5 left -- the left portion of the sling was removed 6 but the right portion was left intact? 7 A. I would just like to look at the 8 operative report. 9 Dr. Smith called it the left arm of the 10 sling and removed a portion on the left side of the 11 urethra. 12 Q. And by "arm," we are not talking about 13 the longer arms that would be -- would accompany 14 the Prolift, for example. We are talking about the 15 section of the sling that would go to the left and 16 to the right of the bladder, correct? 17 A. Yes. 18 Q. And at the time of the revision, she had 19 presented with dyspareunia, correct? 20 A. Yes. 21 Q. And she had, at least according to 22 Dr. Smith, mild evidence of vaginal atrophy, 23 correct? 24 A. Yes. 25 Q. Is it your opinion that atrophy</p>	<p>1 A. Well, we have a few articles that I know 2 are in our list talking about the risk of pain 3 after a posterior repair compared to the ongoing 4 pain risk in the long-term sling data, which runs 5 at about 1 percent; and it is also my experience 6 that when we have patients who have chronic pain 7 after surgery when they've had both prolapse repair 8 and a sling, it's most often the repair in the 9 pelvic muscles. 10 Q. You haven't -- when you say you are 11 comparing the incidence of pain in sling studies, 12 and you are saying it's lower than incidence of 13 pain in posterior repair? 14 A. Yes. 15 Q. Okay. But you are not talking about a 16 study that does a direct comparison of those two, 17 correct? 18 A. Well, we have the Pauls study that we 19 looked at a minute ago which said patients had a 20 posterior repair if they have had pain. It did not 21 matter if they had a sling. The presence of a 22 sling or no incontinence surgery did not make a 23 difference in the pain outcome. 24 Q. But in terms of an analysis of studies, 25 it wouldn't be proper to just take one study done</p>
<p style="text-align: center;">Page 99</p> <p>1 contributed to her dyspareunia? 2 A. Yes. Excuse me. Yes. 3 Q. What are you basing that on? 4 A. I base that on experience that vaginal 5 atrophy contributes to dyspareunia. 6 Q. Even mild vaginal atrophy? 7 A. Yes. 8 Q. And on Page 42 -- I believe I may have 9 already asked you this, I just want to be clear -- 10 you indicate that Mrs. Corbet's OAB symptoms 11 preexisted her July 14th, 2011 surgery, correct? 12 A. Correct. 13 Q. And that's just based on -- 14 A. That questionnaire. 15 Q. -- that one question in the 16 questionnaire? 17 In the next paragraph you write, 18 "Further, posterior repair is much more likely to 19 result in ongoing pain than a sling even in the 20 presence of sling exposure." 21 What is that based on? 22 A. That's based on experience and also on 23 literature. 24 Q. Okay. What literature supports that 25 statement?</p>	<p style="text-align: center;">Page 101</p> <p>1 in one group of patients maybe in a different 2 period of time undergoing certain procedures and 3 let's say the incidence was, you know, 5 percent in 4 that study and then go look at a completely 5 different sling study with maybe a different 6 patient population, different products, and if the 7 incident was one study -- was 1 percent in that 8 study, it wouldn't be fair to say that it's -- the 9 difference is 5 percent to 1 percent, correct? 10 MR. SNELL: Form, foundation. 11 A. I would say there -- that may not be the 12 same patient population, granted, but also using -- 13 those numbers are so much higher, and it is also my 14 experience that patients who have prolapse surgery 15 are much more likely to have pain than we see in a 16 patient with a simple sling exposure. 17 Q. Okay. So when you say the posterior 18 repair is much more likely to result in ongoing 19 pain than a sling, you are really sort of basing 20 that on your own feeling based on studies you've 21 reviewed over the years from your own practice 22 experience? 23 MR. SNELL: Form, misstates. Go 24 ahead. 25 A. My own conclusion -- I wouldn't say it's</p>

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<p>1 an emotional feeling -- my conclusion that knowing 2 in my experience of operating on patients for two 3 decades and reading the literature that the rates 4 are much -- that the incidence of pain is almost 5 always going to be directly related to the prolapse 6 repair and not to the sling.</p> <p>7 Q. And have you done any analysis, any 8 attempts to pull the studies you've reviewed or do 9 a meta-analysis of the different studies?</p> <p>10 A. No.</p> <p>11 Q. Are you familiar with the concept of 12 heterogeneity?</p> <p>13 A. Yes.</p> <p>14 Q. And do you know whether the studies that 15 you looked at relating to dyspareunia following 16 posterior repair, were they long-term studies or 17 short-term studies?</p> <p>18 A. I would need to look at those.</p> <p>19 Q. How many studies are we talking about?</p> <p>20 A. More than a couple.</p> <p>21 Q. And what about the -- first off, as a 22 general matter, there is actually very few studies 23 that address the incidence of dyspareunia following 24 pelvic floor surgery or mesh sling surgery, 25 correct?</p>	<p>1 this will take me a few minutes.</p> <p>2 BY MR. GRAND:</p> <p>3 Q. That's all right. I'm not so sure how 4 well I highlighted.</p> <p>5 A. I have groin pain in the meta-analysis 6 by Schimpf, which runs .34 to 6 percent in the 7 various types of incontinence surgeries.</p> <p>8 And in the subsequent study, which is 9 the Schimpf study from 2014, which is the 10 systematic review and meta-analysis, they talk 11 about dyspareunia in retropubic obturator 12 mini-slings or pubovaginal slings, and that is 0 to 13 .99 percent; and the numbers of women in these 14 studies are over 3,000 in total.</p> <p>15 Q. That's not the TTVT retropubic, is it?</p> <p>16 MR. SNELL: Objection, form, 17 foundation.</p> <p>18 A. Two of the studies were retropubic 19 slings, which had about 500 women.</p> <p>20 Q. Okay. Do you know whether those studies 21 actually tracked dyspareunia?</p> <p>22 A. Where they tracked, I don't have those 23 numbers.</p> <p>24 Q. You don't know whether the underlying 25 numbers actually tracked dyspareunia, do you?</p>
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<p>1 MR. SNELL: Objection, form, 2 foundation.</p> <p>3 A. I think there are -- we are gathering 4 quite a bit of evidence in both of those. A long 5 time ago if it wasn't reported, then we never knew 6 the pre-op incidence, but there are not only 7 reports that talk about pre and post-op but also 8 validated questionnaires that are used very 9 commonly in surgical data. So, I wouldn't say it's 10 rare to find it.</p> <p>11 Q. Well, certainly with the older studies 12 it wasn't even asked about, correct?</p> <p>13 A. Right.</p> <p>14 Q. So what are the new studies that you 15 rely on that actually track dyspareunia in patients 16 receiving -- patients implanted with mesh slings?</p> <p>17 A. Do you want to go through them one by 18 one?</p> <p>19 Q. Yeah.</p> <p>20 A. Okay.</p> <p>21 Q. I would like to know what those are.</p> <p>22 THE WITNESS: I'm so sorry. I'm 23 running out of space here.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I did not highlight as well as you, so</p>	<p>1 MR. SNELL: Form.</p> <p>2 A. Meaning they tracked it. Well, it 3 wouldn't be reported in here if it wasn't in the 4 study.</p> <p>5 Okay. I guess I'm not understanding 6 your question. Do I know if they asked pre and 7 post-op? I'm not looking at those studies right 8 now.</p> <p>9 Q. Right. You don't know how it was 10 tracked, correct? You don't know whether it was by 11 questionnaire --</p> <p>12 A. Right.</p> <p>13 Q. -- self-reported, whether it was a 14 validated questionnaire? Do you know whether those 15 studies were long-term or short-term?</p> <p>16 A. For those particular results, so they 17 required a minimum of 12 months followup.</p> <p>18 Q. So one year?</p> <p>19 A. Right.</p> <p>20 Q. Which wouldn't be long-term, correct?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. It is the minimum allowable for 23 long-term. Five years is preferable, but the 24 minimum we want to see is one year.</p> <p>25 Q. For something involving a medical device</p>

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<p>1 do you consider one year a long-term followup?</p> <p>2 MR. SNELL: Asked and answered, form.</p> <p>3 A. It is better than six weeks for sure.</p> <p>4 Q. But would you consider it long-term</p> <p>5 followup?</p> <p>6 A. It's in the range. So, we want five,</p> <p>7 five is ideal, but one year gives us very good</p> <p>8 information. Actually, when we look at the studies</p> <p>9 that are up to five and ten years that report no</p> <p>10 increasing rates of adverse effects related to the</p> <p>11 mesh over a five-year period.</p> <p>12 Q. We are going to talk about those studies</p> <p>13 soon. But based on your review, there are not a</p> <p>14 lot of studies that are addressing dyspareunia in</p> <p>15 women receiving a TVT sling, correct?</p> <p>16 MR. SNELL: Objection, misstates.</p> <p>17 A. There are studies. What I pulled out</p> <p>18 for you is studies involving 500 women with the</p> <p>19 retropubic specifically.</p> <p>20 Q. And those studies aren't comparative</p> <p>21 studies to women who've just had other pelvic floor</p> <p>22 procedures, correct?</p> <p>23 A. No.</p> <p>24 Q. Would you consider Mrs. Corbet to be at</p> <p>25 risk for future erosion?</p>	<p>1 Q. Okay. So, when you said she is not</p> <p>2 using estrogen, you are referring to --</p> <p>3 A. Yeah, the cream.</p> <p>4 MR. GRAND: The cream, okay. I want</p> <p>5 to turn to your supplemental report.</p> <p>6 Let's see. What time is it? It is</p> <p>7 12:05 p.m. This is probably a good time to</p> <p>8 break for lunch.</p> <p>9 THE VIDEOGRAPHER: The time is</p> <p>10 12:06 p.m., and we are going off the video</p> <p>11 record.</p> <p>12 (Lunch recess taken,</p> <p>13 12:06 - 1:06 p.m.)</p> <p>14 A F T E R N O O N S E S S I O N</p> <p>15 THE VIDEOGRAPHER: The time is</p> <p>16 1:06 p.m., and we are back on the video</p> <p>17 record.</p> <p>18 BY MR. GRAND:</p> <p>19 Q. Dr. Elser, were you able to during the</p> <p>20 break look at the reliance list and determine?</p> <p>21 A. We started, but it was a little bit too</p> <p>22 much to get through in one lunch session.</p> <p>23 Q. Okay. I guess I would ask that once you</p> <p>24 have completed it you could forward a revised</p> <p>25 reliance list through counsel.</p>
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<p>1 A. Erosion or exposure?</p> <p>2 Q. Exposure. Well, both. How are you --</p> <p>3 first off, what's the difference to you?</p> <p>4 A. Erosion, it means that the mesh has</p> <p>5 eroded into an organ nearby, such as bladder or</p> <p>6 bowel. Exposure is when the mesh is open into the</p> <p>7 vaginal canal so the epithelium has an opening.</p> <p>8 Q. Do you think she is at future risk for</p> <p>9 either occurring?</p> <p>10 A. I think it's extremely unlikely that she</p> <p>11 will develop an erosion, and the mesh has been cut,</p> <p>12 so it's no longer under tension at all. There is</p> <p>13 no band across, under the bladder that can cut into</p> <p>14 the bladder.</p> <p>15 Is she at risk for future exposure? It</p> <p>16 can happen with aging and more thinning of the</p> <p>17 vaginal epithelium, and she is not using any</p> <p>18 estrogen and she already has atrophy, but we know</p> <p>19 from the long-term studies that the incidence of</p> <p>20 exposure ongoing ten years after a sling does not</p> <p>21 seem to be very high at all; in fact, minimum.</p> <p>22 Q. Is it your position that she is not</p> <p>23 currently using estrogen cream?</p> <p>24 A. I don't know if she is using it right</p> <p>25 now or not.</p>	<p>1 A. Yes.</p> <p>2 Q. Thank you. I want to ask you some</p> <p>3 questions about some of the studies you cite in</p> <p>4 your supplemental report.</p> <p>5 First I want to ask you, under the</p> <p>6 section Cochrane Review, you have written, "The</p> <p>7 Cochrane reviews are of the highest level of</p> <p>8 evidence as demonstrated by the Oxford levels of</p> <p>9 evidence pyramid."</p> <p>10 A. Yes.</p> <p>11 Q. You are familiar with other evidence</p> <p>12 pyramids that would rate randomized clinical trials</p> <p>13 as the highest form of evidence?</p> <p>14 MR. SNELL: Form.</p> <p>15 A. No. This is the one that I usually</p> <p>16 relied on.</p> <p>17 Q. This is the one you rely on. Have you</p> <p>18 seen others?</p> <p>19 A. I've not looked at others.</p> <p>20 Q. Do you view the Crochane review as a</p> <p>21 systematic review or a meta-analysis?</p> <p>22 A. Yes.</p> <p>23 Q. Which?</p> <p>24 A. Oh. Sometimes they are a combination,</p> <p>25 but usually a meta-analysis.</p>

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<p>1 Q. Okay. Now, the specific review you are 2 talking about is the one that came out this year, 3 the Ford review?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. I wanted to ask you some 6 questions about that. I don't know if you have the 7 complete report with you.</p> <p>8 A. I think I do.</p> <p>9 Q. You do. All 250 pages of it?</p> <p>10 A. That's why this book is so fat. Do you 11 want to look at the short report?</p> <p>12 Q. For my purposes -- you may need to refer 13 to the longer report. For my purposes, I'm going 14 to mark into evidence the shorter one.</p> <p>15 A. Okay.</p> <p>16 Q. But I was trying to spare everyone the 17 burden of walking away with a 250-page report. 18 (Elser Exhibit 10 was marked for 19 identification and re-marked as 20 Exhibit 13 at Page 161.)</p> <p>21 BY MR. GRAND:</p> <p>22 Q. I'm going to mark the summary report 23 from the Cochrane website as Elser 10. Can you 24 take a look at that and make sure we are both 25 talking about the same report.</p>	<p>1 tabulated results for the TVT retropubic.</p> <p>2 A. Let me look then. Hold on.</p> <p>3 Do you have a copy of the short form, 4 not the summary?</p> <p>5 Q. Yes. That's right in front of you.</p> <p>6 A. This is the summary, not the short form. 7 There is also a shorter paper.</p> <p>8 Q. That's what I have.</p> <p>9 A. Okay. I don't know if I brought that. 10 Yeah, I have to look at the tables on 11 the short form to answer that directly.</p> <p>12 Q. You don't have that?</p> <p>13 A. I'm still looking.</p> <p>14 MR. SNELL: This is -- we are off the 15 record.</p> <p>16 THE VIDEOGRAPHER: The time is 17 1:14 p.m., and we are off video record. 18 (Discussion was had off the 19 record.)</p> <p>20 THE VIDEOGRAPHER: The time is 21 1:15 p.m., and we are back on the video 22 record.</p> <p>23 BY MR. GRAND:</p> <p>24 Q. So I'm looking at Page 45.</p> <p>25 A. Yes.</p>
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<p>1 A. Okay.</p> <p>2 Q. And this is a summary of the long form 3 report which you are referring to in your report, 4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. On Page 2 of your supplemental 7 report -- are you there?</p> <p>8 A. I am.</p> <p>9 Q. And in that second paragraph you state, 10 "Most recently, an updated Cochrane review for 2015 11 assessed the literature, including RCTs and 12 registries and observed that for TVT the number of 13 procedures reported ranged from 809 to 4281, and 14 there were found to be low rates of major 15 complications."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. When you say "TVT" in this 19 sentence, are you referring to the TVT retropubic 20 or are you referring to all mesh slings?</p> <p>21 A. That would be retropubic.</p> <p>22 Q. How did you arrive at these numbers for 23 the TVT retropubic? I could not find in that -- in 24 the long form report, which I looked at online, I 25 could not find a break down that specifically</p>	<p>1 Q. It's on the section Retropubic Tapes.</p> <p>2 A. Yes.</p> <p>3 Q. So, that was information pulled from 4 registries, correct?</p> <p>5 A. Yes.</p> <p>6 Q. It was not information pulled from 7 randomized controlled clinical trials, correct?</p> <p>8 A. These are reports from registries.</p> <p>9 Q. And there is nothing here that indicates 10 that this was just the TVT retropubic or whether it 11 included other sling -- retropubic sling products?</p> <p>12 MR. SNELL: Form, misstates.</p> <p>13 A. Okay. It doesn't state here 14 specifically what the registries are from, but most 15 of the registries involve the TVT retropubic.</p> <p>16 Q. Okay. But there may be other products 17 involved in here besides the TVT retropubic, 18 correct?</p> <p>19 A. There may be.</p> <p>20 Q. Do you know one way or the other?</p> <p>21 A. No. I would have to re-look at those 22 registries.</p> <p>23 Q. Okay. And does it indicate here how 24 many of these involved short-term trials versus 25 long-term trials?</p>

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<p>1 A. Not on this page. I would have to 2 re-look at those registries.</p> <p>3 Q. And you know that the Cochrane review is 4 somewhat leery of registry data as opposed to 5 randomized clinical control -- randomized control 6 study data, correct?</p> <p>7 MR. SNELL: Form.</p> <p>8 A. I don't know if they are leery.</p> <p>9 Q. Were you aware that only four of the 10 trials had outcomes of greater than five years?</p> <p>11 A. I don't recall that.</p> <p>12 Q. Let's turn to the summary for a moment. 13 If you could turn to the second page of the 14 summary, it says, "These trials show that over 80 15 percent of women with stress urinary incontinence 16 are cured or have significant improvement in their 17 symptoms with either operation for up to five years 18 after surgery."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes.</p> <p>21 Q. And that's referring to comparing the 22 transobturator approach to the retropubic approach?</p> <p>23 A. I don't know if it is comparing them.</p> <p>24 Q. Well, if you look at what this review 25 tried to find out on the first page -- strike that.</p>	<p>1 foundation on that. You mean referenced in 2 this?</p> <p>3 Q. In the Cochrane review, would it 4 surprise you if there were only four trials out of 5 all of the ones reviewed that had data for more 6 than five years?</p> <p>7 A. No.</p> <p>8 Q. If you go down to the section that says 9 "Limitations of the Review."</p> <p>10 A. Yes.</p> <p>11 Q. It said, "Most of our results are based 12 on moderate quality evidence," correct?</p> <p>13 A. Yes.</p> <p>14 Q. "Most trials did not describe their 15 methods clearly, thus leading to some degree of 16 uncertainty in the findings."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. "At present there are only a limited 20 number of randomized controlled trials (these 21 produced the most reliable results) that have 22 published data beyond five years after surgery. 23 This means that evidence about how effective and 24 safe these procedures are in the longer term lags 25 behind the evidence for them in the short and</p>
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<p>1 This study is not comparing midurethral 2 sling procedures to more traditional forms of 3 treating stress urinary incontinence, correct?</p> <p>4 MR. SNELL: Form, misstates the 5 document.</p> <p>6 A. So, this review is about midurethral 7 slings. It's not talking about any traditional 8 repair such as colposuspension or pubovaginal 9 sling.</p> <p>10 Q. Correct. It's comparing transobturator 11 approach versus retropubic approach, correct?</p> <p>12 A. Right.</p> <p>13 Q. And under either approach, 80 percent of 14 women are cured and presumably 20 percent are not, 15 correct?</p> <p>16 A. 80 percent are cured, right, right.</p> <p>17 Q. And you see a little further down it 18 says, "Only a few trials provided information about 19 the effectiveness of these tapes more than five 20 years after surgery."</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes.</p> <p>23 Q. Would you be surprised if there were 24 actually only four trials?</p> <p>25 MR. SNELL: I'm going to object to</p>	<p>1 medium term, up to five years."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. So, would you agree with them that 5 long-term evidence is going to be greater than five 6 years and anything less than that would be short- 7 to medium-term?</p> <p>8 A. They call short- and medium-term up to 9 five years. I would call five years long-term 10 data, and this is still -- the evidence on these 11 slings is still more robust than any evidence we 12 have for the traditional surgery.</p> <p>13 Q. Would you agree that this is an efficacy 14 review and not a safety review?</p> <p>15 MR. SNELL: Object to form, misstates.</p> <p>16 A. They do report on safety, but they talk 17 -- it said that they are -- that what this review 18 tried to find out is that efficacy, how effective 19 they are and the rate of potential complication.</p> <p>20 Q. Right, but it's fair to say in the 21 underlying -- underlying studies they reviewed they 22 didn't all report on the same safety -- safety 23 endpoints?</p> <p>24 MR. SNELL: Form.</p> <p>25 A. They probably didn't all report on the</p>

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<p>1 same efficacy endpoints either. 2 Q. Fair enough. And so when I look at your 3 report and I see basically reprinted that table you 4 were looking at on Page 45, you can't say that that 5 table actually applies to the TTVT retropubic 6 product as opposed to other products that may be 7 included in this? 8 MR. SNELL: Form, misstates. 9 A. I'm sorry. We would look at those 10 registries that it came from, and most of the data 11 is going to be from TTVT because that was what was 12 involved in most of the registries, but it's not 13 all TTVT retropubic. 14 Q. Right, but you can't say that these 15 particular percentages that you give apply to the 16 TTVT product, correct? 17 A. Well, other studies that look at the 18 5- and 10-year data on the TTVT have similar rates. 19 Q. In the Cochrane study which you are 20 citing, you cannot say that these rates apply to 21 the TTVT retropubic product, correct? 22 MR. SNELL: Hold on. Objection, asked 23 and answered, misstates. 24 A. They're reported for retropubic slings. 25 MR. GRAND: Excuse me?</p>	<p>1 (Elser Exhibit 11 was marked for 2 identification as of 11/5/15.) 3 MR. GRAND: Do you want a copy, Burt? 4 MR. SNELL: Actually, I have one in 5 here. I'm good. Thank you. 6 THE WITNESS: Yours is bigger font. 7 I'm going to look at this one. 8 MR. GRAND: Sure. 9 BY MR. GRAND: 10 Q. Now, like the Cochrane review we just 11 looked at, this compares the obturator approach to 12 the retropubic approach, correct? 13 A. Yes. 14 Q. And if you look at, I guess it's Table 1 15 of the study on Page 1256, only five of the studies 16 actually involve the TTVT retropubic, correct? 17 A. That's what it looks like. 18 Q. And in some cases it's comparing it to 19 the TTVT-O; in other cases it's comparing it to 20 other manufacturer's products; correct? 21 A. Yes. 22 Q. And in fact, it looks like there is less 23 than 400 TTVT-R patients implicated at all, correct? 24 A. I haven't added it up, but that looks 25 like a good ballpark.</p>
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<p>1 THE REPORTER: Say it again, please. 2 A. They are reported for retropubic slings, 3 which may not all be TTVT. 4 Q. On the next page of your supplemental 5 report, Page 3, you discuss the Tommaselli 6 meta-analysis? 7 A. Okay. Sorry. I am flipping back and 8 forth here. 9 Q. I can give you a copy of it. 10 A. I have the Tommaselli right here. 11 Q. I'm going to mark a version so it's in 12 the record, but you can feel free to use your own 13 copy. 14 A. Okay. Is yours highlighted? 15 Q. No. My copy is, not yours. 16 A. Okay. 17 Q. Burt would object if I gave you a 18 highlighted copy. 19 A. I'm sorry. What page of the report were 20 you on? 21 Q. I was just referring to Page 3 of your 22 report where you begin to talk about Tommaselli. 23 A. Okay. 24 MR. GRAND: I'll mark this as 25 Elser 11.</p>	<p>1 Q. And only 35 of those patients had 2 followup of five years or greater, correct? 3 A. Well, you have 35 in study number 15. 4 Study number 18 is 60 months, so that's also five 5 years. 6 Q. And 82 of them were at three years, 7 correct? 8 A. (No verbal response.) 9 Q. And it looks like some of these trials 10 involved validated questionnaires and some did not, 11 correct? 12 A. Correct. 13 Q. And in fact, it looks like this involved 14 ten different slings, correct, not just the TTVT-R? 15 A. I counted nine, but okay. 16 Q. You may be correct. I was eyeballing 17 it. In fact, if you look at the next page, 18 Table 3... 19 A. All right. I'm on Table 2, so it's the 20 next page, the next-next page, Table 3. 21 Q. Yes. It lists the number of patients 22 treated and evaluated in the medium-term and 23 long-term per type of device? 24 A. Yes. 25 Q. Then you see for TTVT retropubic for</p>

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<p>1 randomized controlled studies there was 319 2 patients?</p> <p>3 A. Yes.</p> <p>4 Q. And then there is, I guess, 3,482 5 patients from other types of studies?</p> <p>6 A. Yes.</p> <p>7 Q. In your experience, is it good practice 8 to combine studies from randomized controlled -- 9 combine data from randomized controlled clinical 10 trials with other types of studies?</p> <p>11 A. I think other types of studies are still 12 very valuable, and so to gather as much as evidence 13 as we can, which I put all the information 14 together, I think it's wise to look at everything.</p> <p>15 Q. My question is not that it's wise to 16 look at everything. My question is whether -- 17 whether combining the results from all different 18 types of studies will give you accurate 19 information.</p> <p>20 A. It gives us more information.</p> <p>21 Q. But not necessarily accurate?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. The RCTs have limitations as well. I 24 want to look at all the information, long-term 25 studies from surgeons doing lots of TVTs and what's</p>	<p>1 2013 TVT registry. I will mark that as Exhibit 12. 2 (Elser Exhibit 12 was marked for 3 identification as of 11/5/15.)</p> <p>4 MR. GRAND: Do you want a copy of 5 that, Burt?</p> <p>6 MR. SNELL: Let me see if I have. 7 Yeah, I will take a courtesy copy if you have 8 it. Thank you.</p> <p>9 BY MR. GRAND:</p> <p>10 Q. Now, this study attempted to follow up 11 on women who had undergone a TVT retropubic 12 procedure, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And this was basically a registry study?</p> <p>15 A. Well, they've pulled women from the 16 registry and invited them back specifically to 17 answer questions about this study, so it is not 18 strictly a registry study.</p> <p>19 Q. Right. They -- I believe they 20 identified initially 603 women over a four-year 21 period?</p> <p>22 A. Yes.</p> <p>23 Q. Of those, 542 were still alive?</p> <p>24 A. Yes.</p> <p>25 Q. And of those, they included 483 women?</p>
<p style="text-align: center;">Page 123</p> <p>1 available in the RCTs as well.</p> <p>2 Q. Well, presumably you did. You've cited 3 this study, correct?</p> <p>4 A. Right.</p> <p>5 Q. So, you think this was a sound 6 approach --</p> <p>7 A. It's an approach to get --</p> <p>8 Q. -- or meta-analysis?</p> <p>9 A. -- as much data as we can to learn about 10 the outcome.</p> <p>11 Q. So, with respect to the conclusions you 12 cite in your report about the number of vaginal 13 erosions at 2.1 percent for retropubic, that's for 14 all retropubic regardless of product, correct?</p> <p>15 A. Correct.</p> <p>16 Q. So, if the TVT were higher and another 17 product were lower, it would have averaged out to 18 2.1, correct?</p> <p>19 A. That is potentially, but since most of 20 the studies we know out there which are TVT, not 21 retropubic, because it has been out there the 22 longest, it probably skews the evidence toward 23 whatever was really TVT results.</p> <p>24 Q. Set that aside.</p> <p>25 I want to ask you about the Svenningsen</p>	<p style="text-align: center;">Page 125</p> <p>1 A. Yes.</p> <p>2 Q. Do you know why they excluded some 3 women?</p> <p>4 A. I know that some were not willing to 5 participate, but I would have to look back, look 6 through to see why.</p> <p>7 Q. And of the 483 women, 327 actually 8 attended a clinical consultation and the other 156 9 participated by phone, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Now, did you review the questionnaires 12 from this study?</p> <p>13 A. No.</p> <p>14 Q. Do you know whether they actually asked 15 these women about dyspareunia?</p> <p>16 A. I don't know.</p> <p>17 Q. And in this study, de novo urgency 18 increased from 4 percent in the first 6 to 12 19 months following surgery up to almost 15 percent at 20 the 10-year followup point, correct?</p> <p>21 A. As I believe is included in my report, 22 over ten years' time women this age especially have 23 a natural incidence of increasing urge incontinence, so I would not conclude that that's because they had a TVT.</p>

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<p>1 Q. And in terms of -- well, sorry. I just 2 lost my place. One second. 3 And the way that they evaluated 4 complications was to ask the women what 5 complications they remembered over a 10-year 6 period; is that correct? 7 A. By questionnaire, it was by 8 questionnaire. 9 Q. Now, the authors of this did not 10 conclude that the increased incontinence was due to 11 a natural increased incontinence that would happen 12 over time, correct? 13 MR. SNELL: Form. 14 Q. They didn't reach the same conclusion 15 you did? 16 MR. SNELL: Same objection. 17 A. I'm on Page 1275. "Our study 18 illustrates the difficulties encountered when 19 evaluating long-term results in an aging 20 population. Recurrence of stress incontinence as 21 well as recurrence or occurrence of prolapse 22 urgency and urge incontinence over time could be 23 consequences of the surgical procedure ten years 24 previously as well as the effects of normal 25 deterioration of the pelvic floor caused by</p>	<p>1 A. Well, I'm not a person who works in a 2 lab studying materials all day, but I am familiar 3 with the Amid classifications and which type of 4 mesh seem to heal well in the pelvis as compared to 5 other types of mesh. 6 Q. Okay. You looked at other 7 classifications beside the Amid classification? 8 A. No. 9 Q. Have you ever looked at studies that 10 show what the pore size of the mesh is under 11 stress? 12 MR. SNELL: Form. 13 A. I have seen that. 14 Q. Are you going to be offering opinions at 15 trial about the pore sizes of the mesh? 16 A. If I'm asked about them. 17 MR. SNELL: And I will say she has 18 identified as macroporous, so those opinions 19 will be elicited at trial. 20 MR. GRAND: All right. We will take 21 that up in motion practice. 22 BY MR. GRAND: 23 Q. You don't consult as a materials expert, 24 correct? 25 MR. SNELL: Form.</p>
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<p>1 advancing age."</p> <p>2 Q. And on Page 1277 they note that the 3 14.9 percent of women reporting de novo urgency is 4 consistent with incontinence rates in other TTVT 5 publications, correct?</p> <p>6 A. Right.</p> <p>7 Q. So, you would agree with that?</p> <p>8 Regardless of what you would attribute it to, you 9 would agree that that number is consistent with 10 other TTVT studies?</p> <p>11 A. Yes.</p> <p>12 Q. Now, on Page 8 of your supplemental 13 report --</p> <p>14 MR. SNELL: I'm sorry. I didn't hear 15 what page.</p> <p>16 MR. GRAND: Page 8.</p> <p>17 THE WITNESS: Okay. I'm there.</p> <p>18 BY MR. GRAND:</p> <p>19 Q. You give some opinions on the lower half 20 of the page regarding biocompatibility of the mesh 21 and whether the mesh is macroporous and 22 monofilament. Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. You are not a materials expert, correct?</p> <p>25 MR. SNELL: Form.</p>	<p>1 A. No.</p> <p>2 Q. And you have never designed a mesh, 3 correct?</p> <p>4 A. No.</p> <p>5 Q. And you haven't studied explants of 6 mesh, correct?</p> <p>7 MR. SNELL: Form.</p> <p>8 A. No.</p> <p>9 Q. And have you done any research into the 10 effects of -- scratch that.</p> <p>11 Strike that.</p> <p>12 Okay. On the next page you state, "I 13 have used the TTVT for about 17 years and noticed no 14 clinical difference between mechanical and 15 laser-cut mesh."</p> <p>16 Have you reviewed internal documents by 17 Ethicon in which they know the difference between 18 mechanical and laser-cut mesh?</p> <p>19 MR. SNELL: Actually, objection, 20 foundation on that one.</p> <p>21 BY MR. GRAND:</p> <p>22 Q. Have you reviewed any of the Ethicon's 23 internal documents relating to the differences 24 between mechanical and laser-cut mesh?</p> <p>25 A. It's been a while. I have read some,</p>

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<p style="text-align: right;">Page 130</p> <p>1 but I'm really referring to our clinical 2 experience, and we don't see a difference. 3 Q. How do you know the difference between 4 mechanical and laser-cut mesh out of the package? 5 A. The edges appear smooth, appear more 6 solid and smoother on the laser cut. 7 Q. Okay. So, you can tell if I were to 8 hand you two pieces of mesh which was mechanical 9 and which was laser cut? 10 A. I think so. 11 Q. And you have tracked that in your 12 practice? 13 A. We know when the changes were made in 14 the different devices that we're using, and we 15 don't see a change in our cure rates or our 16 exposure rates. 17 Q. Have you tracked which of your patients 18 received laser-cut mesh versus mechanical-cut mesh? 19 A. No. 20 Q. In fact, you haven't tracked recently 21 any of your patients who have received a TVT 22 retropubic laser cut versus mechanical cut, 23 correct? 24 MR. SNELL: Form. 25 A. I haven't tracked recently. I have not</p>	<p style="text-align: right;">Page 132</p> <p>1 A. I don't -- I think I've heard that 2 before, but it was not something I knew. 3 Q. Okay. So, this isn't something you have 4 actually tracked in your practice, correct? 5 MR. SNELL: Form. 6 A. Right. I just said I've not tracked it. 7 Q. Okay. So, when you said we have noticed 8 no clinical difference, it's just that you haven't 9 noticed? 10 A. Over time. 11 Q. Well, you haven't used the TVT 12 retropubic in two years? 13 A. I would notice if all of a sudden our 14 exposure rate is going way up or our pain rate is 15 going up or our cure rate is going down or our 16 retention rate is going up, and I have not noticed 17 a clinical change in our sling patients. 18 Q. In your next sentence you say, "I have 19 reviewed photographs of the mesh being stretched 50 20 percent, and it is my opinion that this is a 21 laboratory scenario as the mesh is not similarly 22 stretched during implantation." 23 Did I read that correctly? 24 A. Yes. 25 Q. Is it your view that the mesh cannot be</p>
<p style="text-align: right;">Page 131</p> <p>1 checked. 2 Q. Well, you said that your 4.5 percent 3 figure goes back about two years, correct? 4 A. Correct. 5 Q. There is not going to be any TVT 6 patients included in that, correct? 7 MR. SNELL: Same objection. 8 A. So you are talking about mechanical cut? 9 Q. We are talking about -- yeah. 10 A. Oh. You said laser cut. 11 Q. Well, retropubic, which is both 12 mechanical and laser cut. 13 A. Well, I've not pulled and sat and looked 14 at, oh, this is my pile of patients with this data 15 and this is my pile with that data, but I certainly 16 pay a lot of attention to our results; and when 17 products change or we are using a new product, 18 we'll -- we'll know it right away if we are seeing 19 different outcomes and stop and then take a look 20 and say, hey, what's going on, what's different. 21 But we have not had to do that when retropubic went 22 to laser cut or now we went to Exact because we are 23 not seeing different outcomes. 24 Q. Are you aware that the TVT retropubic is 25 still available in mechanical cut?</p>	<p style="text-align: right;">Page 133</p> <p>1 stretched in other ways besides implantation? 2 A. Once it's implanted, it's very hard to 3 stretch. 4 Q. There is no stresses that may occur 5 through movement of the body? 6 A. Once the plastic sheaths are off, it's 7 hard to move it, it's hard to adjust it, so that it 8 would even dramatically change our post-op 9 counseling to patients on what restrictions they 10 have after surgery. Because it's so hard to move, 11 we think it would be very difficult for them to 12 distort it in any significant way once the plastic 13 is removed. 14 And we were always instructed to take 15 care to not stretch or distort it before 16 implanting, and in the original TVT, the plastic 17 sheath which was overlapped in the middle, it could 18 separate prematurely; and if it separated and got 19 pulled, like if an assistant took it out carelessly 20 out of the package, I would put that away and start 21 fresh with a new product because it was stretched 22 abnormally before it was implanted, and that's not 23 what we want. So, when we place it with the 24 plastic sheath intact, it does not distort or 25 stretch.</p>

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<p>1 Q. So, your statement that in your opinion 2 it's a laboratory scenario and the mesh is not 3 similarly stretched during implantation, do you 4 have any data or testing to support that?</p> <p>5 A. No. This is my experience from having 6 looked at the mesh in the lab, looking at videos of 7 it stretching when placed on machines and looking 8 at people taking it out of the package and 9 stretching it too far before it's implanted.</p> <p>10 Q. When have you looked at mesh in the lab?</p> <p>11 A. It would be in cadaver courses. We 12 would take it and do whatever we could to try and 13 break or stretch it.</p> <p>14 Q. When was the last time you had a cadaver 15 course in mesh or you taught a cadaver course in 16 mesh?</p> <p>17 A. Maybe three years ago.</p> <p>18 Q. You taught a cadaver course with a TVT 19 retropubic three years ago?</p> <p>20 A. Yes.</p> <p>21 Q. The Svennigsen study you cite --</p> <p>22 MR. SNELL: Is that the one we had earlier?</p> <p>23 MR. GRAND: Yeah.</p> <p>24 MR. SNELL: Did you mark that one 12</p>	<p>1 Q. And you see Sigurd Kulseng-Hanssen also 2 received travel grants from Pfizer and Gynecare?</p> <p>3 A. Yes.</p> <p>4 Q. For -- on Page 12 of your supplemental 5 report you state, "The risk of dyspareunia, pain 6 and sexual dysfunction with TTVT is very small and 7 less than the pubovaginal sling and Burch 8 colposuspension."</p> <p>9 Do I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Other than the two sources you 12 cited there, what studies are you pointing to as 13 authority for that?</p> <p>14 A. I better look at the other 10-year studies to look at the dyspareunia rate.</p> <p>15 Q. And what do you characterize as very 16 small in terms of risk?</p> <p>17 A. Well, for Schimpf's report it was less than -- it was like 2 percent or less in the studies.</p> <p>18 We have a Angioli study, which is a five-year followup looking at TVT versus obturator with 3 percent dyspareunia after five years.</p> <p>19 I was looking for the Nilsson's 17-year study. I know it's in here.</p>
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<p>1 or 13?</p> <p>2 THE WITNESS: 12.</p> <p>3 MR. GRAND: 12.</p> <p>4 BY MR. GRAND:</p> <p>5 Q. All the authors are Gynecare or Ethicon 6 consultants, correct?</p> <p>7 MR. SNELL: Foundation.</p> <p>8 A. I don't know.</p> <p>9 Q. Did you read the study?</p> <p>10 A. I did. I don't remember that part.</p> <p>11 Q. On Page 1277 there is a section called "Conflict of Interest." It says Rune Svennigsen once received travel grants from Johnson & Johnson among other companies. Do you see that?</p> <p>12 A. I see that, yes. I know that's very common in Europe to attend conferences and be treated by a company.</p> <p>13 Q. You see Anne C. Staff --</p> <p>14 A. Yes.</p> <p>15 Q. -- has the received speaker fees, travel grants, advisory board fees and remuneration for clinical drug studies from multiple companies, including Johnson & Johnson/Gynecare. Do you see that?</p> <p>16 A. Yes.</p>	<p>1 Q. Would that and the other study you just 2 mentioned be your sources other than the one you 3 referred to in your report?</p> <p>4 A. It's the main one looking at long-term, that gave us long-term data to talk about the ongoing rates of dyspareunia and pain.</p> <p>5 Okay. When I find that, I will tell you.</p> <p>6 MR. GRAND: I do not have further questions right now.</p> <p>7 EXAMINATION</p> <p>8 BY MR. SNELL:</p> <p>9 Q. Dr. Elser, my name is Burt Snell. I 10 represent Ethicon and Johnson & Johnson. I just 11 want to ask you some followup questions, and let's 12 start on the topic we were just discussing. 13 Mr. Grand asked you about data upon which you were 14 relying concerning the low rates of pain or 15 dyspareunia with the TVT retropubic device. 16 Turn, if you would, to Page 5 of your 17 report.</p> <p>18 MR. GRAND: Talking about the 19 supplemental?</p> <p>20 MR. SNELL: Yes.</p> <p>21 THE WITNESS: Got it.</p>

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<p style="text-align: right;">Page 138</p> <p>1 BY MR. SNELL:</p> <p>2 Q. In the bottom paragraph you cite to a 3 paper by Unger this year, 2015?</p> <p>4 A. Yes. Thank you.</p> <p>5 MR. GRAND: Sorry. I just don't see 6 it. Oh, got it.</p> <p>7 THE WITNESS: Bottom of Page 5.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. And what was the rate of reoperation for 10 pain or dyspareunia in that study?</p> <p>11 A. There was far less. It was 2.7 percent 12 overall, but pain or dyspareunia specifically was 13 .2 percent.</p> <p>14 Q. Is that a study you are relying on for 15 your opinions regarding a low risk of pain or 16 dyspareunia?</p> <p>17 A. Yes.</p> <p>18 Q. There is another study, Nguyen 2012. 19 I'm not sure if I'm pronouncing that correctly.</p> <p>20 A. Nguyen.</p> <p>21 Q. Nguyen, okay. So I was totally off.</p> <p>22 A. It's N-g-u-y-e-n.</p> <p>23 Q. And that was a study regarding 24 reoperation or the need for reoperation due to 25 complications?</p>	<p style="text-align: right;">Page 140</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And is that something you cited 3 for the opinion that you believe that the rate of 4 pain or dyspareunia with TTVT is lower than that 5 with the Burch or the fascial sling?</p> <p>6 A. Yes.</p> <p>7 MR. GRAND: Just to be clear, are we 8 talking now about TTVT retropubic or all TTVT 9 products?</p> <p>10 MR. SNELL: TTVT, TTVT retropubic.</p> <p>11 BY THE WITNESS:</p> <p>12 A. It says synthetic midurethral sling, but 13 again, most of their data would come from TTVT data.</p> <p>14 BY MR. SNELL:</p> <p>15 Q. And let's take a look at the Tommaselli 16 paper that Mr. Grand marked as Elser No. 11, and I 17 would like to just follow up on that point you just 18 made, Doctor.</p> <p>19 If you would turn to page -- well, the 20 page with Table 3 that Mr. Grand and you were 21 discussing. Do you see that?</p> <p>22 A. Yeah, Page 1258.</p> <p>23 Q. If you look at Table 3, now, you had 24 made the point that the vast majority of data on 25 retropubic comes from the TTVT retropubic studies,</p>
<p style="text-align: right;">Page 139</p> <p>1 A. Yes, and their reoperation for pain was 2 .04 percent.</p> <p>3 Q. Is that a study upon which you are 4 relying?</p> <p>5 A. Yes.</p> <p>6 Q. Do you find those studies reliable?</p> <p>7 A. Yes, those are reliable.</p> <p>8 Q. You already discussed the Schimpf SGS, 9 systematic review and meta-analysis, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And the American Urologic Association 12 stress incontinence guidelines and meta-analysis?</p> <p>13 A. Yes.</p> <p>14 Q. I think you identified, those are some 15 of the items that you are relying upon for the low 16 risk of pain or dyspareunia; is that right?</p> <p>17 A. Yes.</p> <p>18 Q. I'm just going to hand you, and I will 19 give it to Mr. Grand. Why don't we just mark it. 20 Is this the AUA updated table you were talking 21 about with regard to rates of pain and sexual 22 dysfunction amongst the various stress 23 incontinence --</p> <p>24 A. Yes.</p> <p>25 Q. -- surgeries? Okay.</p>	<p style="text-align: right;">Page 141</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. Is this table and does this systematic 4 review and meta-analysis support your opinion that 5 the vast majority of retropubic data flows from the 6 original TTVT retropubic device?</p> <p>7 A. Yes. On a total of retropubic slings, 8 there were 3974 retropubic slings and 3801 of those 9 are retropubic TTVT.</p> <p>10 Q. So just so we are clear, 3,801 were 11 patients treated with the TTVT retropubic device?</p> <p>12 A. Yes.</p> <p>13 Q. And adding up all the retropubic 14 devices, it was 3,974?</p> <p>15 A. Yes.</p> <p>16 Q. Fair to say that in the long-term data 17 the TTVT device makes up well over 95 percent of the 18 data available?</p> <p>19 A. Yes. It's been around the longest and 20 the most studied.</p> <p>21 Q. And so when these studies are reporting 22 rates of complications, whether they use the word 23 "TTVT, tension-free vaginal tape" or "retropubic tape," is it fair to say that that data speaks to the TTVT retropubic device?</p>

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<p>1 MR. GRAND: Objection.</p> <p>2 A. Yes. Unless it specifically states</p> <p>3 otherwise, we assume the data is retropubic TVT.</p> <p>4 Q. And is that because over 95 percent of</p> <p>5 the retropubic data flows from the TVT retropubic</p> <p>6 device?</p> <p>7 A. Yes.</p> <p>8 Q. You discussed Table 1 with Mr. Grand. I</p> <p>9 just think just pointing out for the record, there</p> <p>10 was a study in there. I didn't see that you two</p> <p>11 discussed it, but reference number 17, the longest</p> <p>12 study with followup, 100 months. Did that involve</p> <p>13 the TVT device?</p> <p>14 A. Yes, it did.</p> <p>15 Q. And you didn't really discuss Table 2,</p> <p>16 but Table 2 has various other studies and it runs</p> <p>17 two pages; and fair to say the vast majority of</p> <p>18 those studies also include the TVT device?</p> <p>19 A. Yes, most of those are TVT.</p> <p>20 Q. Is there any retropubic device that has</p> <p>21 ever been available to surgeons like yourself that</p> <p>22 has more data than the Ethicon TVT retropubic</p> <p>23 device?</p> <p>24 A. No.</p> <p>25 Q. Is there any retropubic device that has</p>	<p>1 guidelines by the various professional societies?</p> <p>2 A. Yes.</p> <p>3 Q. You and Mr. Grand discussed the</p> <p>4 Ford/Cochrane review from this year. Do you recall</p> <p>5 that?</p> <p>6 A. Yes.</p> <p>7 Q. I just had a quick question. I think it</p> <p>8 was on Page 45. And so is it fair to say the vast</p> <p>9 majority of retropubic data is also from the TVT</p> <p>10 retropubic device?</p> <p>11 A. Yes.</p> <p>12 Q. And at Page 45 where you reference the</p> <p>13 registries -- I will let you get to it.</p> <p>14 A. Yeah, yes.</p> <p>15 Q. You reference and said that those</p> <p>16 registries would include and pertain to the TVT</p> <p>17 retropubic device?</p> <p>18 A. Yes.</p> <p>19 Q. For instance, Kuuva 2002, is that a</p> <p>20 registry that you are familiar with?</p> <p>21 A. Yes.</p> <p>22 Q. You recognize that as one of the</p> <p>23 earliest Scandinavian registries on the original</p> <p>24 TVT retropubic device?</p> <p>25 MR. GRAND: Objection.</p>
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<p>1 nearly the amount of long-term data as you define</p> <p>2 long-term as the TVT retropubic device?</p> <p>3 A. No.</p> <p>4 MR. GRAND: Objection, foundation.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. Doctor, you have been regularly, you</p> <p>7 told us, reading the medical literature for</p> <p>8 decades?</p> <p>9 A. Yes.</p> <p>10 Q. Do you stay abreast in your field with</p> <p>11 regard to stress incontinence devices?</p> <p>12 A. I do.</p> <p>13 Q. You have looked at various meta-analyses</p> <p>14 and systematic reviews?</p> <p>15 A. Yes.</p> <p>16 Q. And in all of those, have you ever seen</p> <p>17 any retropubic device that has nearly the amount of</p> <p>18 data that the TVT retropubic device has?</p> <p>19 A. No.</p> <p>20 Q. Are meta-analyses and systematic reviews</p> <p>21 a recognized approach to evaluating clinical data</p> <p>22 in your field of urogynecology?</p> <p>23 A. Yes.</p> <p>24 Q. Do you rely upon Cochrane reviews,</p> <p>25 systematic reviews and meta-analyses and the</p>	<p>1 A. Yes, I do.</p> <p>2 Q. Well, I mean, you've presented on the</p> <p>3 TTVT retropubic device, including clinical data on</p> <p>4 it, to other doctors?</p> <p>5 A. Yes.</p> <p>6 Q. You have presented with slides that</p> <p>7 actually referenced and discuss the Kuuva registry</p> <p>8 for TTVT?</p> <p>9 A. Yes.</p> <p>10 Q. You were familiar with that long before</p> <p>11 I ever contacted you?</p> <p>12 A. Yes.</p> <p>13 Q. All right. And a question was posed</p> <p>14 about the retropubic data in the Cochrane review,</p> <p>15 not the website but the actual document. I'm going</p> <p>16 to read it to you. It says, "From the above list</p> <p>17 of registries, the tension-free vaginal tape."</p> <p>18 Would that be the TTVT device we have been</p> <p>19 discussing today?</p> <p>20 A. Yes.</p> <p>21 Q. The number of procedures reported range</p> <p>22 from 809 to 4,281 and are found below, and you</p> <p>23 included that information in your report?</p> <p>24 A. Yes.</p> <p>25 Q. I believe Mr. Grand asked you a question</p>

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<p>1 about whether the Cochrane group was wary -- or I 2 don't mean to use the wrong term. 3 A. Leery. 4 Q. -- leery about registry data as opposed 5 to randomized controlled data. 6 My question to you is this: Did you 7 cite in your report where the Cochrane group states 8 that the rates in these registries are largely of 9 the same order as those reported in the trials 10 included in this review? 11 A. Yes. 12 Q. What's the significance of that, if any, 13 with regard to how reliable those registries are? 14 A. They seem to be keeping track of the 15 data to the same caliber as the long-term RCTs 16 because we are getting similar rates of success and 17 complications. 18 Q. And is that something you look for in 19 your analyses, consistency in various types of 20 data? 21 A. Yes. 22 Q. Mr. Grand asked you a couple questions 23 about the Svenningsen 2013 study that involved -- 24 that involved the TTVT retropubic device? 25 A. Yes.</p>	<p>1 Q. And I believe you testified it's your 2 opinion that the old label was just as adequate as 3 the new label? 4 A. Yes. 5 Q. I believe a question was asked about the 6 implanting surgeon's training. Let me ask you 7 this: Did you have an understanding as to whether 8 the implanting surgeon was a medical doctor? 9 A. He has "M.D." after his name. 10 Q. Do you know whether he was -- had 11 undergone further training like a residency in 12 urogynecology or gynecology? 13 A. His deposition CV had stated he had done 14 an OB/GYN residency. 15 Q. And when you talked about the basic or 16 the risks that flow across incontinence surgeries 17 that a surgeon who is going to do incontinence 18 surgery would be expected to know of, would those 19 risks be taught during gynecologic residency? 20 A. Yes. 21 MR. GRAND: Objection, foundation. 22 Q. Did you undergo a gynecologic residency? 23 A. I did. 24 Q. Did you learn about all of those basic 25 risks that you identified here today?</p>
<p style="text-align: center;">Page 147</p> <p>1 Q. I just have two quick questions about 2 that one. The duration of followup is 129 months, 3 as it states in the abstract, correct? 4 A. Yes. 5 Q. Did you find this study reliable? 6 A. I did. 7 Q. And on the third page they state that 8 the methods, definitions and units in this study 9 conform to the standards recommended by IUGA and 10 the ICS Joint Report on Terminology For Female 11 Pelvic Floor Dysfunction. 12 Do you see that? 13 A. Yes. 14 Q. Is that a way of discussing whether or 15 not this study was conducted within the norms of 16 your field of expertise? 17 A. It helps us compare apples to apples, so 18 instead of that reporting to us, oh, these patients 19 were all dry, they are using the definitions and 20 the scales created by these societies to help us 21 communicate our data. 22 Q. You were asked some questions about the 23 2015 IFU versus the IFU that was in effect at the 24 time of Ms. Corbet's surgery, correct? 25 A. Yes.</p>	<p style="text-align: center;">Page 149</p> <p>1 A. Yes. 2 Q. Would those include wound complications, 3 like the suture erosions and -- 4 A. Yes. 5 Q. Okay. And not to date you, but did you 6 undergo your residency before -- before TTVT was 7 available? 8 A. Yes. 9 Q. Has the risk of wound complications, 10 dyspareunia, pain, voiding dysfunction, de novo 11 detrusor overactivity, are those -- have those long 12 been known in your field based on basic, elemental 13 gynecologic training and knowledge? 14 A. Yes. 15 Q. You were asked questions about the 16 hematoma that Ms. Corbet had, and I think some of 17 the questions by Mr. Grand seemed to indicate or 18 were prefaced with the terms "after the device was 19 placed." 20 At the time -- strike that. 21 At the time the TTVT retropubic device 22 was placed in Ms. Corbet, she underwent a prolapse 23 procedure as well? 24 A. Yes. 25 Q. Wouldn't you say that was a posterior</p>

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<p>1 colporrhaphy?</p> <p>2 A. Yes.</p> <p>3 Q. A perineoplasty?</p> <p>4 A. Yes.</p> <p>5 Q. And are the risks -- is there a risk of</p> <p>6 hematoma with those procedures?</p> <p>7 A. Absolutely.</p> <p>8 Q. And have you looked at the medical</p> <p>9 literature regarding the risk of hematoma with</p> <p>10 those prolapse surgeries?</p> <p>11 A. I have, and there is several reports</p> <p>12 like an posterior colporrhaphy with risk up to 30</p> <p>13 percent (inaudible) --</p> <p>14 THE REPORTER: Would you please</p> <p>15 repeat.</p> <p>16 THE WITNESS: With posterior</p> <p>17 colporrhaphy, the risk is up to 30 percent in</p> <p>18 the literature of a hematoma.</p> <p>19 BY MR. SNELL:</p> <p>20 Q. And have you looked -- obviously a lot</p> <p>21 of TTV studies and the registries and things like</p> <p>22 that address the rates of hematomas, correct?</p> <p>23 A. Yes.</p> <p>24 Q. The Ford/Cochrane review we just looked</p> <p>25 at said pelvic hematoma occurred in .7 to 1.9</p>	<p>1 A. No.</p> <p>2 Q. Fair to say in your mind they are the</p> <p>3 same product?</p> <p>4 A. Yes.</p> <p>5 Q. They utilize the same Prolene</p> <p>6 polypropylene macroporous mesh?</p> <p>7 A. Yes.</p> <p>8 Q. Have you done any literature searches --</p> <p>9 Mr. Grand asked you about mechanical-cut and</p> <p>10 laser-cut mesh. Have you done any literature</p> <p>11 searches that identify in any clinical studies in</p> <p>12 women that there is a clinically significant</p> <p>13 difference depending upon how the edges of the TTV</p> <p>14 mesh were cut?</p> <p>15 A. No.</p> <p>16 Q. And for TTV, I'm talking about TTV</p> <p>17 retropubic device.</p> <p>18 A. Right. I could not find any clinical</p> <p>19 difference in the literature.</p> <p>20 Q. And therefore, let me ask you, the 4.5</p> <p>21 percent reoperation rate that you went back and</p> <p>22 analyzed in your practice and found, is that</p> <p>23 consistent or inconsistent with the data you have</p> <p>24 seen on TTV retropubic?</p> <p>25 MR. GRAND: Objection.</p>
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<p>1 percent of women. My question to you is, have you</p> <p>2 formulated an opinion about the overall risk of</p> <p>3 pelvic hematoma after the TTV retropubic device,</p> <p>4 and if so, what is that percentage based on your</p> <p>5 synthesis of all of the materials you have read and</p> <p>6 brought here and are relying on?</p> <p>7 A. It seems to be less than 5 percent and</p> <p>8 certainly much lower risk of hematoma with the</p> <p>9 sling than with a prolapse repair.</p> <p>10 Q. Mr. Grand asked you about the</p> <p>11 supplemental report. I just want to make sure.</p> <p>12 I'm not sure maybe I heard things correctly or not.</p> <p>13 I think in response to Mr. Grand's</p> <p>14 questions you said you spent 25 to 30 hours</p> <p>15 drafting your supplemental report. Now, maybe I've</p> <p>16 got that right or wrong. I don't know. I just</p> <p>17 want clarification. How much time did you spend on</p> <p>18 your supplemental report?</p> <p>19 A. So, I spent reading this literature and</p> <p>20 the records and getting ready for the deposition</p> <p>21 about 25 to 30 hours, but preparing the</p> <p>22 supplemental report itself, five or six hours.</p> <p>23 Q. The TTV retropubic device and the TTV</p> <p>24 Exact device, do you view those as significantly</p> <p>25 different?</p>	<p>1 A. It is really consistent with the -- with</p> <p>2 the other data.</p> <p>3 Q. You were asked some questions about</p> <p>4 whether you were an expert or not, and with regard</p> <p>5 to material science you testified you didn't work</p> <p>6 in a lab.</p> <p>7 My question to you is this: Do you</p> <p>8 believe you have specialized or scientific</p> <p>9 knowledge on the use of materials in the pelvic</p> <p>10 floor -- in the treatment of pelvic floor</p> <p>11 disorders?</p> <p>12 A. Yes.</p> <p>13 Q. Have you reviewed the medical literature</p> <p>14 with regard to the use of various materials in the</p> <p>15 treatment of stress urinary incontinence?</p> <p>16 A. Yes, I have.</p> <p>17 Q. How long have you been knowledgeable</p> <p>18 about the different types of materials that a</p> <p>19 surgeon like yourself can potentially use to treat</p> <p>20 stress urinary incontinence?</p> <p>21 A. Well, it's been almost 20 years since I</p> <p>22 first saw Gortex used as a sling, so I have been</p> <p>23 looking at different mesh materials implanted in</p> <p>24 the pelvis for a long time.</p> <p>25 Q. Is it fair to say you have also</p>

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<p>1 evaluated thousands of patients and done thousands 2 of surgeries using various materials? And I'm 3 talking about pelvic floor surgery. 4 A. Yes. 5 Q. Do you believe you are an expert in the 6 clinical application, the efficacy and safety of 7 materials used to treat stress urinary 8 incontinence? 9 A. Yes. 10 Q. You were asked a question about 11 epidemiology, and you testified that you didn't 12 think you were an expert in epidemiology. My 13 question to you is this: What did you mean by 14 that, first of all, when you answered that you 15 weren't an expert in epidemiology? 16 A. It's not my chosen career. I don't go 17 out looking for jobs in epidemiology, but certainly 18 as part of our literature it's something we 19 evaluate when we are looking at studies and how to 20 apply treatments or evaluations in women. 21 Q. And have you analyzed the medical 22 literature, including epidemiologic studies, with 23 regard to the TVT device and other stress urinary 24 incontinence procedures? 25 A. Yes.</p>	<p>1 Q. You were asked about clinical trial work 2 that you had done, and I believe you identified 3 different clinical trials that you were involved in 4 the design of? 5 A. Yes. 6 Q. Do you know how to interpret clinical 7 trial designs? 8 A. Yes. 9 Q. Do you -- is that -- strike that. 10 Is understanding the levels of evidence 11 and the different types of clinical trials one can 12 employ or review, is that a basic competency in 13 your field? I'm talking about to the treatment of 14 stress urinary incontinence. 15 A. Yes. 16 Q. So, do you feel you are an expert in 17 epidemiology in clinical trials as it applies to 18 studies evaluating female pelvic medicine and 19 reconstructive surgery? 20 A. Yes. 21 MR. SNELL: Let's stop and just change 22 the tape. 23 THE VIDEOGRAPHER: The time is 24 2:20 p.m. This is the end of Tape 2 and we 25 are going off the video record.</p>
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<p>1 Q. Were you trained on how to evaluate 2 epidemiologic data in your medical school or 3 residency? 4 A. Yes. 5 Q. Is that actually part of the core 6 competencies of urogynecology in the field? 7 A. It is. I would like to clarify it, 8 because I was asked when was the last time I took a 9 statistic course, which was a long time ago during 10 my fellowship, but when we just took our boards for 11 our female pelvic medicine and reconstructive 12 surgery in 2013, there was a very substantial 13 amount of statistical questions, and our review 14 course was substantially based -- I mean, focused 15 on statistics and epidemiology. 16 Q. Do you know how to interpret 17 epidemiologic and statistical data? 18 A. Yes. 19 Q. And as a reviewer of articles for 20 various journals as well as your regular reading of 21 the medical literature, do you analyze the 22 statistics and the statistical significance and 23 things such as cure rates with regard to those 24 treatment modalities? 25 A. Yes.</p>	<p>1 (Recess taken, 2:20 - 2:29 p.m.) 2 (Elser Exhibit 14 was marked for 3 identification as of 11/5/15.) 4 THE VIDEOGRAPHER: The time is 5 2:29 p.m. This is the beginning of Tape 3, 6 and we are back on the video record. 7 BY MR. SNELL: 8 Q. Dr. Elser, we were earlier talking about 9 various studies that you are relying on that 10 support your opinion that Ms. Corbet is at a low 11 risk of future surgery or corrective surgery and 12 that there is a low rate of long-term pain. 13 Turn, if you would, to Page 3 of your 14 supplemental report. 15 A. Okay. 16 Q. And if you want to look at Exhibit 11 as 17 well, my question pertains to the Tommaselli paper 18 from this year regarding medium- and long-term 19 outcomes. This is the study we were discussing 20 where you testified more than 95 percent of the 21 retropubic data comes from the TVT retropubic 22 device. 23 A. Right. 24 Q. And in your report you say that 25 persistent or pain lasting beyond the immediate</p>

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<p>1 postoperative period was present in only 13 women 2 with retropubic midurethral sling out of 3,974, 3 Table 3. Do you see that? 4 A. Yep. 5 Q. Is that consistent or are you relying 6 upon that data for your opinion that the risk of 7 long-term pain and reoperation is very low? 8 A. Yes. 9 Q. I just calculated that, and I will 10 represent it's 0.3 percent for that rate, whether 11 you attribute all 13 women to TVT or not. 12 My question to you is, is that 0.3 13 percent consistent with other data you have seen 14 with that similar risk? 15 A. Yes, it is, very low risk. 16 Q. Were the American Urologic -- strike 17 that. 18 The American Urological Association 19 stress incontinence, female stress incontinence 20 guidelines, the update, I just want to mark for the 21 record that that was marked as Elser 14 -- 22 A. Yes. 23 Q. -- that you were referring to earlier, 24 and I believe Mr. Grand has something that he is 25 updating.</p>	<p>1 A. Right. 2 Q. Do you recall that? 3 A. I do recall that. 4 MR. SNELL: The tables -- I will go 5 ahead and mark this as Exhibit No. 15 just so 6 you can reference it and we can save time. 7 MR. GRAND: Do you have a copy of it? 8 MR. SNELL: I will give it to you. 9 (Elser Exhibit 15 was marked for 10 identification as of 11/5/15.) BY MR. GRAND: 12 Q. Doctor, do you have that paper handy 13 by -- 14 A. I don't. 15 MR. SNELL: We can go off the record. 16 THE VIDEOGRAPHER: The time is 17 2:36 p.m., and we are going off the video 18 record. 19 (Discussion was had off the 20 record.) 21 THE VIDEOGRAPHER: The time is 22 2:38 p.m., and we are back on the video 23 record. BY MR. SNELL: 25 Q. Dr. Elser, we have marked the Karram and</p>
<p style="text-align: center;">Page 159</p> <p>1 MR. GRAND: Are you done? 2 MR. SNELL: No, no. I just want to 3 make sure the record is clear that why I am 4 doing 14 as opposed -- 5 MR. GRAND: The Cochrane summary which 6 I had previously marked as Elser 10, we are 7 changing that to Elser 13 to correct my 8 mistake in marking exhibits. 9 MR. SNELL: And that's why I've now 10 marked the AUA Guideline as Exhibit 14. So 11 thank you, Mr. Grand. 12 (The document marked at Page 110 as 13 Exhibit 10 was re-marked as Exhibit 14 13.) BY MR. SNELL: 16 Q. You were asked a question about the risk 17 of dyspareunia with the posterior prolapse surgery 18 that Ms. Corbet underwent, and I believe you 19 testified that it was much higher than the rate 20 seen with the TVT retropubic; is that correct? 21 A. Yes. 22 Q. And I think you cite to probably in both 23 of your reports, I thought it was a meta-analysis 24 by Micky Karram and Christopher Maher, Surgery For 25 Posterior Vaginal Wall Prolapse.</p>	<p style="text-align: center;">Page 161</p> <p>1 Maher paper on posterior repair, correct? 2 A. Yes. 3 Q. What exhibit is that? 4 A. 15. 5 Q. If you look at Tables 1 and 2, which 6 pertain to normal posterior colporrhaphy and a 7 site-specific repair, you wrote in your report that 8 the overall rates of dyspareunia is 18 percent for 9 either way. Do you recall that? 10 A. Yes. 11 Q. Is that a meta-analysis that you are 12 relying on? 13 A. Yes. The Table 1 refers to traditional 14 posterior colporrhaphy. When they added up all the 15 studies, the dyspareunia rate was 18 percent and 16 the site-specific repair, the dyspareunia rate for 17 all the studies average was also 18 percent. 18 Q. You mentioned earlier the Kahn paper. 19 That's another paper, the Kahn paper, you are 20 relying on with regard to the dyspareunia rates for 21 posterior repair? 22 A. Yes. The Kahn paper is cited in this 23 table. 24 MR. SNELL: I would like to mark as -- 25 what exhibit are we on?</p>

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<p>1 THE REPORTER: 16. 2 (Elser Exhibit 16 was marked for 3 identification as of 11/5/15.) 4 BY MR. SNELL: 5 Q. Exhibit 16 is the registry by Kuuva and 6 Nilsson. My question to you is very simple. Is 7 that the registry we earlier discussed that 8 specifically pertains to the TVT retropubic device? 9 A. Yes. 10 (Elser Exhibit 17 was marked for 11 identification as of 11/5/15.) 12 BY MR. SNELL: 13 Q. I would like to mark as Exhibit 17 14 another document, and before I do, so Mr. Grand 15 marked various DVDs, thumb drives and some 16 materials you brought here today in response to 17 their request that you produce your file? 18 A. Yes. 19 Q. And as I look to the left, there are 20 multiple binders that have not been marked but that 21 you bought those as well? 22 A. Yes. 23 Q. And are those materials that you are 24 relying on for your opinions in this case? 25 A. Yes.</p>	<p>1 professional practice that you present to other 2 doctors with regard to stress and urge 3 incontinence? 4 A. Yes. This was at a -- at an ACOG 5 course. 6 Q. Questions were asked of you about the 7 pathology report after -- 8 THE VIDEOGRAPHER: Excuse me, 9 counselor. Your microphone. 10 BY MR. SNELL: 11 Q. Some questions were asked about the 12 pathology report following the mesh excision in 13 Mrs. Corbet's case. Do you recall that? 14 A. Yes. 15 Q. And that there was chronic inflammation 16 reported in the pathology report? 17 A. Yes. 18 MR. SNELL: Can I have another exhibit 19 sticker. 20 BY MR. SNELL: 21 Q. So, Dr. Elser, when the original surgery 22 was done, that was a transvaginal surgery where the 23 placement of TVT and the posterior colporrhaphy was 24 accomplished? 25 A. Yes.</p>
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<p>1 Q. You've also brought what's been marked 2 as Elser Exhibit 17. Can you just tell us what 3 that is? 4 A. The subpoena request asked me to bring 5 any lectures that I've given on topics of 6 incontinence, so this was a update I gave on 7 urogynecology in September of this year. 8 Q. Is that a lecture you would have given, 9 is that to patients or doctors or who? 10 A. It was to OB/GYNs. 11 Q. Okay. Does that pertain -- does that 12 lecture pertain to stress incontinence? 13 A. It talks about incontinence, both urge 14 and stress, but does specifically discuss stress 15 incontinence. 16 Q. And did you present to gynecologic 17 surgeons on the TVT retropubic device and other 18 midurethral slings? 19 A. Yes, I did discuss slings, midurethral 20 slings in this talk. 21 Q. Did you present and discuss with other 22 surgeons clinical study data regarding both stress 23 incontinence and urge incontinence treatments? 24 A. I did. 25 Q. And that's just part of your normal</p>	<p>1 Q. And that was in July 2011 -- 2 A. Yes. 3 Q. -- as you wrote in your reports? 4 A. It was also a cystocele repair, because 5 we keep saying a sling and posterior repair, but it 6 was a cystocele repair as well as the posterior 7 repair. 8 Q. And does the cystocele repair -- is that 9 a prolapse surgery? 10 A. Yes. 11 Q. Okay. Does it have all those same risks 12 you identified for posterior repair; namely, wound 13 complications, pain, effect on urination and 14 bladder function? 15 A. Yes. 16 Q. And did you see that at the time of the 17 original surgery some of Mrs. Corbet's vaginal 18 tissue was excised and sent to pathology as well? 19 A. Yes. 20 (Elser Exhibit 18 was marked for 21 identification as of 11/5/15.) 22 BY MR. SNELL: 23 Q. I would like to give you Exhibit 18. Do 24 you recognize that as the pathology report from the 25 initial date of surgery when Mrs. Corbet had her</p>

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<p style="text-align: right;">Page 166</p> <p>1 prolapso surgeries and the placement of the 2 retropubic sling and the perineoplasty? 3 A. Yes. 4 Q. And does that pathology report document 5 that she had mild chronic inflammation in her 6 vaginal tissues before the TTVT retropubic sling had 7 even been placed and grown in? 8 A. Yes. 9 Q. You opined that Mrs. Corbet's prognosis 10 is good and she is at a very low risk of surgery in 11 the future; is that correct? 12 A. Yes. 13 Q. And is that based upon all of the -- are 14 you relying on the TTVT studies we have been 15 discussing today and that are cited in your reports 16 and are contained in the thumb drive and materials 17 produced? 18 A. Yes. 19 MR. SNELL: I will turn over the 20 witness. I will just note for the record 21 there are literally seven or eight binders 22 that we haven't marked, but you are free to, 23 if you would like. 24 MR. GRAND: I will say on the record 25 that I have reviewed those binders and that</p>	<p style="text-align: right;">Page 168</p> <p>1 about some of these larger review studies you have 2 cited in your report, they all rely on studies 3 whose primary endpoint was efficacy, correct? 4 A. They primarily do. I won't say that 5 they all do. 6 Q. Okay. The majority of the studies had 7 efficacy endpoints as the primary outcome, correct? 8 A. Yes. 9 Q. Can you point to a single TTVT retropubic 10 study where its primary endpoint was a safety 11 endpoint? 12 A. Not right now. I would have to look 13 through them. 14 Q. And in fact, most of the studies that 15 have been included in these reviews that we have 16 been talking about today as noted by the Cochrane 17 report are short- to medium-term studies, correct? 18 MR. SNELL: Object to form, misstates. 19 A. Most of the studies are short- to 20 medium- term as defined by Cochrane, and most of 21 the studies use efficacy as the endpoint which is 22 easier to measure; and because we are seeing such a 23 low complication rate, the ability to do an RCT 24 with your primary endpoint being a complication 25 that's running at 2 percent would be very difficult</p>
<p style="text-align: right;">Page 167</p> <p>1 they contain literature that is already cited 2 in the reliance materials that I have, so I 3 didn't feel a need to mark them and burden our 4 court reporter with having to transport tons 5 of binders. 6 MR. SNELL: That's fine. 7 MR. GRAND: Just a couple of quick 8 question. 9 FURTHER EXAMINATION 10 BY MR. GRAND: 11 Q. The pathology report that Mr. Snell just 12 showed you, the difference between that one and the 13 pathology report that was done at the time of 14 revision was a foreign body response, correct, 15 reaction? 16 A. Yes. 17 Q. So, one may have -- while they both may 18 have inflamed tissue, one has inflamed tissue 19 because of a foreign body reaction, correct? 20 MR. SNELL: Objection, foundation, 21 form. 22 A. One has foreign body response associated 23 with a foreign body being there. 24 Q. Thank you. Now, we have talked about a 25 lot of studies today, and I want to -- when we talk</p>	<p style="text-align: right;">Page 169</p> <p>1 to carry out. 2 Q. Have you looked at the underlying 3 studies in the Cochrane review? 4 A. Many of them; not every single one. 5 Q. You are aware that they collected 6 different safety endpoints in those studies, 7 correct? 8 A. Meaning that it was not the same in each 9 study? 10 Q. Yes. 11 A. Yes. 12 Q. So therefore, it would be very hard to 13 combine those studies for any safety analysis, 14 correct? 15 MR. SNELL: Objection, form. 16 A. They combine the data, but it's not all 17 the exact same data points. 18 MR. GRAND: No further questions. 19 FURTHER EXAMINATION 20 BY MR. SNELL: 21 Q. Mr. Grand asked you just a couple of 22 questions there, and I want to follow up. 23 You reviewed a lot of studies about the 24 TTVT retropubic device, correct? 25 A. Yes.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Q. Whether or not their primary endpoint 2 was safety or complications, did those studies 3 report on safety and complications? 4 A. Yes. 5 Q. Did they report rates of complications? 6 A. Yes. 7 Q. Did they discuss perioperative and 8 operative data, how long it took to do the surgery, 9 the discharge times, things of that nature? 10 A. Many of them did. 11 Q. Are those important data in your field 12 as a urogynecologist? 13 A. Yes. 14 Q. Is that information you considered in 15 forming your opinions about TTVT retropubic? 16 A. Yes. 17 Q. And the question was asked about 18 specifically a study regarding the primary endpoint 19 of safety. Do the registries like the Kuuva 20 Nilsson registry we discussed, is one of their 21 primary functions to report safety in very large 22 patient groups? 23 A. Yes. 24 Q. And do they do that, in fact? 25 A. Yes.</p>	<p style="text-align: right;">Page 172</p> <p>1 that study and find out whether there are errors in 2 their analysis or whether they properly accounted 3 for certain factors which might affect their 4 statistical analysis of the study? 5 A. Up to a certain level. 6 Q. Up to a certain level, but you wouldn't 7 hold yourself out as an expert to perform those 8 tasks, correct? 9 MR. SNELL: Form. 10 A. I would consult with the statistician. 11 Q. You would consult with a statistician. 12 With respect to safety endpoints, there 13 is a difference in a study that has a primary 14 endpoint of safety and a study that just collects 15 data about safety as a secondary endpoint, correct, 16 or even a post hoc analysis, correct? 17 A. Right, because it may not be powered to 18 measure differences in that secondary outcome. 19 Q. Okay. So -- exactly. So, some of the 20 studies that we have been talking about today may 21 not have even been powered to capture safety 22 endpoints, correct? 23 MR. SNELL: Form. 24 A. They might have been powered to tell a 25 difference between two in between, safety between</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. And are those data reliable specifically 2 to the TTVT retropubic device? 3 A. They appear to be. 4 MR. SNELL: No further questions. 5 FURTHER EXAMINATION 6 BY MR. GRAND: 7 Q. The registry data, registry data can 8 only collect followup safety endpoints if the 9 patient returns to that physician participating in 10 the registry, correct? 11 A. Yes, and that's why the registries are 12 so beautiful in Norway where as far as a captive 13 audience and it's not so easy for a patient to go 14 somewhere else. 15 Q. With respect to -- there is a difference 16 between being competent in an area and being an 17 expert in an area, correct? 18 A. I guess it depends on your definition. 19 Q. Okay. Well, the NIH isn't running to 20 you asking you to design clinical trials, asking 21 you to design clinical trials for them, are they? 22 A. No. 23 Q. And while you feel competent to review a 24 clinical study in a published article, would you 25 also feel competent to do an in-depth analysis of</p>	<p style="text-align: right;">Page 173</p> <p>1 two procedures. It doesn't mean they are not 2 effectively collecting safety data. 3 Q. Right. And in fact, many of the studies 4 involved a small number of patients and only were a 5 year-long, if not less, correct? 6 A. Many of them. 7 Q. And those studies may not be adequately 8 powered to find certain complications that may 9 arise with mesh, correct? 10 MR. SNELL: Form. 11 A. It's possible. 12 Q. In fact, some of the studies we were 13 looking at were only three-month studies, correct? 14 A. Some were. 15 MR. SNELL: Foundation, I think, on 16 three month. 17 Q. In a three-month study would you expect 18 the rate of -- strike that. 19 MR. GRAND: I have no further 20 questions. 21 FURTHER EXAMINATION 22 BY MR. SNELL: 23 Q. Doctor, with regard to your ability to 24 interpret and understand clinical trials, is it 25 correct that you present to other surgeons on</p>

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<p>1 clinical trial data and how to analyze those 2 studies?</p> <p>3 A. How to interpret the data, yes.</p> <p>4 Q. Yes. I'm sorry. And in your role as 5 being on the FDA advisory -- strike that.</p> <p>6 In your role in consulting with the FDA, 7 are you expected to and do you analyze clinical 8 trial data regarding gynecologic devices?</p> <p>9 A. Yes. Let me be clear. I'm not here as 10 an FDA representative.</p> <p>11 Q. No, that's fine. I don't know the scope 12 of it.</p> <p>13 And with regard to the primary analyses, 14 in your report you were referencing several of the 15 studies like Jonsson Funk that interrogated these 16 captive audience databases. Do you recall that?</p> <p>17 A. Yes.</p> <p>18 Q. And do you recall that those studies, 19 their primary goal, primary power, what they did is 20 they integrated huge databases with thousands of 21 patients, and they specifically looked for safety 22 endpoints like what was the rate of sling revision, 23 removal due to exposure, voiding dysfunction?</p> <p>24 A. Yes.</p> <p>25 Q. On Page 5 there is a study from Welk</p>	<p>1 M. Elser, and we are off the video record. 2 (At 2:58 p.m. the deposition was 3 concluded.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 2015, and you state that it has a 3.3 percent 2 10-year cumulative reoperation rate?</p> <p>3 A. Yes.</p> <p>4 Q. Did you find that similar to the 9-year 5 3.7 percent rate by Jonsson Funk?</p> <p>6 A. Very similar.</p> <p>7 Q. And just so we are clear, you and 8 Mr. Grand were discussing how many patients were in 9 various studies, but do you recall that that study 10 by Welk was a Canadian database that analyzed over 11 50,000 women who had received sling placements?</p> <p>12 A. Yes.</p> <p>13 Q. And so they evaluated safety endpoints, 14 and that was what they primarily reported on, 15 safety endpoints in over 50,000 women getting 16 slings with a 10-year followup?</p> <p>17 A. Yes.</p> <p>18 Q. Are you aware of any data like that for 19 the Burch or autologous slings?</p> <p>20 A. No.</p> <p>21 MR. SNELL: That's all I have.</p> <p>22 MR. GRAND: No further questions.</p> <p>23 THE VIDEOGRAPHER: The time is 24 2:58 p.m. This is the end of Tape 3. It's 25 also the end of the deposition of Dr. Denise</p>	<p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER 2 I, PAULINE M. VARGO, a Certified 3 Shorthand Reporter of the State of Illinois, 4 C.S.R. No. 84-1573, do hereby certify: 5 That previous to the commencement of the 6 examination of the witness, the witness was duly 7 sworn to testify the whole truth concerning the 8 matters herein; 9 That the foregoing deposition transcript 10 was reported stenographically by me, was thereafter 11 reduced to typewriting under my personal direction 12 and constitutes a true record of the testimony 13 given and the proceedings had; 14 That I am not a relative, employee, 15 attorney or counsel, nor a relative or employee of 16 such attorney or counsel for any of the parties 17 hereto, nor interested directly or indirectly in 18 the outcome of this action. 19 CERTIFIED TO THIS 10th DAY OF NOVEMBER, 20 A.D., 2015.</p> <p>21</p> <p>22 _____</p> <p>23 Pauline M. Vargo, RPR, CRR 24 Illinois CSR No. 84-1573 25</p>

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